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The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers

Treatment Improvement Protocol (TIP) Series 18

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DHHS Publication No. (SMA) 95-3047
Printed 1995

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[Front Matter]

[Title Page]

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This publication was written under contract number ADM 270-92-0006 from the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration (SAMHSA). Duiona R. Baker, M.P.H., and David L. Griffith, M.Ed., M.S., R.N., served as the CSAT Government project officers.

The opinions expressed herein are the views of the consensus panel members and do not reflect the official position of CSAT or any other part of the U.S. Department of Health and Human Services (DHHS). No official support or endorsement of CSAT or DHHS for these opinions or for particular instruments of software that may be described in this document is intended or

should be inferred. The guidelines proffered in this document should not be considered as substitutes for individualized patient care and treatment decisions.

A Note to Readers

Substance abusers -- be they dependent on alcohol or drugs or both -- are so stigmatized in our society that those of us who work in the substance abuse field have grown accustomed to doing our important and valuable work in relative isolation from others. In recent years, however, our patients and employees have been ravaged by a very public disease, tuberculosis (TB). To meet the threat that TB poses to both our patients and employees, many alcohol and other drug (AOD) treatment programs have entered collaborative relationships with appropriate State, local, and private agencies. Born less of legal than of practical and ethical obligations, those efforts comport with the AOD field's tradition of compassion, respect, responsibility, and commitment to health. In light of that tradition -- and given that most substance abuse treatment programs have but the most limited budgets -- we believe that it would be in everyone's interest if more AOD programs were to collaborate with both the public and private sectors in the effort to prevent the transmission of TB in the AOD setting.

It was in the spirit of collaboration that the Center for Substance Abuse Treatment (CSAT) convened a consensus panel of AOD providers, public health officials, and others in New York City during the week of May 16-20, 1994. That panel produced this document, one in a series of Treatment Improvement Protocols (TIPs) that CSAT has funded over the past few years. Intended for AOD administrators, AOD staff, public health officials, corrections officials, and State substance abuse officials, this TIP summarizes the latest advice and recommended protocols for dealing with the threat of TB in the AOD setting. We believe that the recommendations and advice in this document can help smooth the way for further and improved collaboration between the AOD field and others in preventing not only TB but other communicable diseases in the treatment setting.

In closing, I should like to thank the members of the Federal resource panel and the consensus panel for giving so much of their valuable time to this project. I should also like to thank the many field reviewers who took time to give detailed suggestions for improving this document. Finally, I should like to thank Felix Lopez, Esquire, of the Legal Action Center of New York City, Inc., for his editorial assistance and for endeavoring to revise this document in accordance with the suggestions of both the consensus panel members and the field reviewers.

David H. Mulligan
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What Is a TIP?

CSAT Treatment Improvement Protocols (TIPs) are prepared by the Quality Assurance and Evaluation Branch to facilitate the transfer of state-of-the-art protocols and guidelines for the treatment of alcohol and other drug (AOD) abuse from acknowledged clinical, research, and

administrative experts to the Nation's AOD abuse treatment resources.

The dissemination of a TIP is the last step in a process that begins with the recommendation of an AOD abuse problem area for consideration by a panel of experts. These include clinicians, researchers, and program managers, as well as professionals in such related fields as social services or criminal justice.

Once a topic has been selected, CSAT creates a Federal resource panel, with members from pertinent Federal agencies and national organizations, to review the state of the art in treatment and program management in the area selected. Recommendations from this Federal panel are then transmitted to the members of a second group, which consists of non-Federal experts who are intimately familiar with the topic. This group, known as a non-Federal consensus panel, meets in Washington for 5 days, makes recommendations, defines protocols, and arrives at agreement on protocols. Its members represent AOD abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A Chair for the panel is charged with the responsibility of ensuring that the resulting protocol reflects true group consensus.

The next step is a review of the proposed guidelines and protocol by a third group whose members serve as expert field reviewers. Once their recommendations and responses have been reviewed, the Chair approves the document for publication. The result is a TIP reflecting the actual state of the art of AOD abuse treatment in public and private programs recognized for their provision of high quality and innovative AOD abuse treatment.

This TIP on guidelines to assist AOD treatment providers in dealing with legal and ethical issues posed by the tuberculosis epidemic is the 18th published by CSAT since a treatment improvement initiative began. The reader may be interested in the sixth TIP in the series, Screening for Infectious Disease Among Substance Abusers, which also deals with tuberculosis, particularly in chapters 6, 7, and 8. This TIP represents another step by CSAT toward its goal of bringing national leadership to bear in the effort to improve AOD abuse treatment.

Other TIPS may be ordered by contacting the National Clearinghouse for Alcohol and Drug Information (NCADI), (800) 729-6686 or (301) 468-2600; TDD (for hearing impaired), (800) 487-4889.

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Foreword

The Treatment Improvement Protocol Series (TIPs) fulfills CSAT's mission to improve alcohol and other drug (AOD) abuse and dependency treatment by providing best practices guidance to clinicians, program administrators, and payers. This guidance, in the form of a protocol, results from a careful consideration of all relevant clinical and health services research findings, demonstration experience, and implementation requirements. A panel of non-Federal clinical researchers, clinicians, program administrators, and patient advocates employs a consensus process to produce the product. This panel's work is reviewed and critiqued by field reviewers as it evolves.

The talent, dedication, and hard work that TIPs panelists and reviewers bring to this highly

participatory process have bridged the gap between the promise of research and the needs of practicing clinicians and administrators. We are grateful to all who have joined with us to contribute to advance our substance abuse treatment field.

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The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
Treatment Improvement Protocol (TIP) Series 18

Chapter 1 -- Introduction

This TIP is the culmination of a process that began with the convening of a Federal Resource Panel composed of State and Federal public health officials and alcohol and other drug (AOD) treatment providers. That Federal resource panel identified the basic issues to be discussed in this document, namely, screening for TB, methods for communicating with State public health officials regarding AOD patients with active TB, and guidelines for educating AOD program staff about TB. In May 1994, a second panel -- a consensus panel -- met to discuss the issues identified by the Federal resource panel and to develop practical guidelines for helping AOD treatment providers and public health officials prevent the transmission of TB in the AOD setting. The consensus panel consisted of representatives of State agencies, AOD treatment providers, and State TB control officials. Consensus panel work groups focused on the effect of TB on AOD treatment programs as providers of patient services, the effect of TB on AOD treatment programs as employers, and the effect of TB on the relationship between AOD providers and the public health field. This document is the product of the consensus panel's deliberations.

Purpose of the TIP

The purpose of this TIP is to give practical ethical and legal advice to AOD treatment providers about cooperating with public health officials and others in preventing the transmission of TB in AOD treatment facilities. Given that not all AOD programs are alike -- physically, demographically, or in terms of the services they provide -- and given that the risk of TB varies from one program to the next, it is not assumed that everything in this document will be relevant or useful for all treatment providers. Nevertheless, to the extent that all AOD providers have an interest in stemming the spread of TB in their facilities, and to the extent that all AOD providers operate under similar ethical and legal obligations, it is hoped that this document will

1. Illuminate some of the more important issues raised by the threat of TB in the AOD setting
2. Promote collaboration between AOD treatment providers and others in the fight against TB
3. Lead to a safer AOD work place.

Toward that end, this TIP will set forth basic information about tuberculosis, explain how AOD treatment providers and others can collaborate without violating Federal laws regarding the confidentiality of alcohol and other drug abuse treatment records, outline the TB-related services required of most substance abuse treatment providers, and discuss steps that substance abuse treatment providers can take to promote safety in the workplace. In keeping with the demanding ethics of the substance abuse treatment field, this document attempts to tell the reader not just what must be done, but what should be done.

Audience

This document is intended for policymakers, the staff of State agencies that fund and regulate substance abuse treatment programs, corrections officials, administrators and employees of substance abuse treatment programs, clinicians serving special care populations, and infectious disease officials.

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Chapter 2 -- Summary of Recommendations

Substance abuse providers are obligated by Federal and State laws (and their own ethics) to provide or arrange for TB screening and followup for their patients, to report communicable diseases, including TB, to local or State public health officials, to protect the confidentiality of their patients, and to provide a safe workplace for their employees and others. This TIP makes a number of recommendations that will help providers reconcile (and comply with) those potentially conflicting obligations. Those recommendations are summarized below.

Collaboration Between the AOD and Public Health Fields

The alcohol and other drug (AOD) and public health fields should collaborate with each other to prevent the transmission of TB in the AOD setting. Collaboration would benefit shared patients, the public at large, the public health field, and AOD treatment providers. The Federal confidentiality laws do not prevent the two fields from collaborating with each other. To promote a good working relationship, the AOD and public health fields should:

- Use patient consent and qualified service organization agreements to share patient-identifying information
- Develop cooperation agreements that describe the roles and responsibilities of each with respect to TB screening, treatment, and followup
- Cross-train each other's workers
- Develop mutually beneficial propaganda (e.g., brochures and posters)
- Collaborate on record keeping procedures
- Develop lists of useful contacts.

Providing TB Services for AOD Patients

AOD programs are required to provide or arrange for TB-related services for their patients. Those services must include mechanisms for screening, evaluating, treating, and following up patients with active disease or patients in treatment. In providing those services, AOD programs should:

- Be sure to detect, isolate, and treat patients and applicants with active TB
- Take care not to discriminate against those with TB who are not infectious and pose no threat of transmitting TB to others
- Use intake questionnaires that focus on the signs and symptoms of TB and on past TB involvement including treatment, if any, and preventive therapy, if any
- Provide purified protein derivative (PPD) skin testing for all high-risk applicants

- Ensure that applicants and patients with positive PPDs receive proper medical evaluation
- Report suspected and confirmed cases of active TB to local or State public health officials, as mandated by State law
- Remove or isolate patients with active disease
- Ensure that patients in need of TB treatment receive it
- Use directly observed therapy to promote patient adherence to recommended treatment or preventive therapy regimens
- Monitor patients in treatment or preventive therapy for adherence, efficacy of treatment, and side effects
- Screen patients periodically for TB
- Educate patients about the risk of TB in the facility, the signs and symptoms of TB, TB treatment, preventive therapy, and the side effects of TB medications
- Keep careful records of PPDs, evaluations, x-rays, diagnoses, etc.
- Collaborate with public health officials and others to ensure appropriate screening, evaluation, treatment, monitoring, and record keeping.

Toward a Safe Workplace

To promote a safe workplace, AOD providers should collaborate with public health officials and workplace safety specialists. Providers must be sure to exclude from the workplace any patients and employees who have active TB disease. In general, AOD providers should:

- Develop a site-specific TB risk assessment
- Develop a written TB-infection control policy based on that assessment
- Employ a hierarchy of controls to prevent the spread of TB in the facility, placing particular emphasis on administrative controls
- Screen new employees for TB
- Counsel employees about the risk of TB at the facility
- Arrange for annual or more frequent PPDs, depending on the risk of TB at the facility, for all employees
- Analyze all PPD conversions
- Try to determine the source or sources of TB exposures at the site, if any
- Train employees regarding the facility's TB-infection control policy
- Arrange to review safety practices at regular intervals or whenever there is reason to believe that TB may have been transmitted on the premises
- Take care not to discriminate against employees with noninfectious TB
- Respect employee confidentiality

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Chapter 3 -- The Facts About Tuberculosis

Alcohol and drug treatment programs have an ethical and legal obligation to help prevent the transmission of tuberculosis in their facilities. To meet those obligations, program managers and staff must familiarize themselves -- and their patients -- with the facts about tuberculosis. This chapter outlines the facts regarding the transmission, detection, and treatment of TB.

Reemergence of Tuberculosis as a Serious National Problem

After declining steadily for about 30 years, the number of new cases of TB reported in the United States began to grow in the mid-1980s.[1] From 1985 to 1993, the number of new cases of TB reported in the United States grew by about 14 percent.[2] The Centers for Disease Control and Prevention (CDC) attributes that increase to at least four factors:

1. The HIV epidemic
2. Continuing immigration from countries where TB is common
3. The transmission of TB in congregate settings, such as homeless shelters and correctional facilities
4. The deterioration of the Nation's health care infrastructure.

The increase in the incidence of TB has been accompanied by an increase in the incidence of drug-resistant and multidrug-resistant strains of TB (MDR-TB).[3] Unlike drug-sensitive strains, drug-resistant TB can be very difficult to treat -- even when the patient is completely adherent to the recommended regimen.[4] Persons who develop drug-resistant TB tend to stay infectious longer than those with drug-sensitive strains. They are therefore apt to expose more people to infection.

What Causes TB?

TB is caused by an organism called *Mycobacterium tuberculosis or M. tuberculosis. (M. tuberculosis* organisms are sometimes called tubercle bacilli.) Infection by *M. tuberculosis* does not necessarily lead to active TB disease or contagiousness. Only 10 percent of immune-competent persons infected with TB will develop active or contagious TB disease.[5] (Of course, the risk of developing active disease is much greater for persons who are immunosuppressed or have human immunodeficiency virus (HIV).) The vast majority of TB-infected persons -- about 90 percent -- will never develop active or infectious disease and will never pose a threat of transmitting TB to others.

In some cases, infection with *M. tuberculosis* will lead to active disease within a relatively short time; in others, it may take years before active disease develops, if at all. The progression from infection to disease often depends on individual characteristics, e.g., one's immunologic or

general medical status, the recency of one's infection with TB, whether one has a particular medical condition (for instance, cancer or diabetes), and whether one is on an immunosuppressive therapy.

How Is TB Transmitted?

TB is a communicable disease that is spread primarily by tiny airborne particles (droplet nuclei) expelled into the air by someone with infectious pulmonary or laryngeal TB disease, typically through coughing or sneezing. Depending on ventilation and other factors, these tiny droplets can remain suspended in the air for several hours. Should another person inhale them, he or she may become infected with TB. The probability of transmission will be related to the infectiousness of the person with TB, the environment where the exposure occurred, the duration of the exposure, and the susceptibility of the host.

Who Is at High Risk for Exposure and Infection?

Although anyone can be exposed to or get TB, some people are at higher risk for both exposure and infection (though exposure does not necessarily result in infection). These higher risk groups include, among others:

- The close contacts of someone who is infectious
- Immigrants from areas where TB is common, such as Asia, Africa, and Latin America[6]
- The poor
- The medically underserved
- Racial and ethnic minorities[7]
- Persons living in congregate settings, such as correctional facilities or residential AOD programs
- Alcoholics and persons who inject drugs[8]
- The homeless
- Persons with HIV infection
- Persons who are exposed to infectious TB on the job.

Of those infected with TB, the following run an especially high risk of developing active TB disease:

- Persons with HIV
- Persons whose infection is relatively recent (within the previous 2 years)
- Injection drug users
- Those with a history of inadequately treated TB.

Persons infected with both HIV and TB have the highest known risk factor for developing active TB disease.[9] Whereas TB-infected persons who are not HIV-positive run a 10 percent lifetime risk of developing active disease, those with both TB and HIV run a 7 percent to 10 percent chance *per year* of developing active disease.[10]

How Do We Screen for TB Infection?

Mantoux Tuberculin Skin Test

The preferred method for detecting TB infection -- and the only way to diagnose TB infection before it progresses to active disease -- is a skin test using the Mantoux technique.[11] That technique involves the injection of a small amount of purified protein derivative (PPD) just beneath the surface of the skin of the forearm. (The PPD poses no threat of disease or TB infection to the test subject, regardless of the test subject's HIV status.) The result of the test can be read by a trained health care worker within 48 to 72 hours of the time of the injection. Generally, an immune-competent person infected with TB for more than 2 to 10 weeks will produce an immune response to the PPD that manifests itself through the development of an induration at the site of the injection. (An induration is an area of raised, swollen, or hardened skin.[12]) A person not infected with TB will usually produce no induration in response to the PPD. Indurations are measured and recorded in millimeters.

Reading and Classifying the Tuberculin Reaction

In most cases, a positive reaction to a tuberculin skin test will show that the test subject is TB-infected. Whether a reaction is classified as positive will depend on the size of the induration and the risk factors for infection or disease of the person being tested. Thus, a reaction of 5 mm or more is positive in:

- Persons whose chest x-rays suggest previous TB disease
- Persons who are HIV-positive
- Persons with risk factors for HIV infection
- Close contacts of persons with infectious TB
- Injection drug users whose HIV status is unknown.

A reaction of 10 mm or more is positive in:

- Injection drug users who are HIV seronegative
- Persons with known medical risk factors (other than HIV disease) for developing infectious TB, e.g., diabetes mellitus
- Persons from medically underserved or low income populations, including such high-risk minority groups as Asians, Pacific Islanders, African Americans, Latinos, and Native Americans
- Immigrants from countries where TB is common
- Residents of long-term care facilities
- Health care workers in facilities where TB is present
- The homeless.

All others will be considered to have had a positive reaction to the skin test only if they develop an induration of 15 mm or more.[13]

What About Immunosuppressed Individuals?

Between 10 and 25 percent of persons with TB do not react, or react only mildly, to tuberculin skin testing.[14] Thus, the fact that someone does not react to the test does not necessarily mean that he or she is not infected. In fact, about one-third of persons with HIV infection -- and 60 percent of those with AIDS -- have a reaction to tuberculin skin testing that in other circumstances would probably not be considered positive. The inability of some immunosuppressed individuals to mount a response to tests such as the tuberculin skin test is known as "anergy." Anergy can be caused by HIV infection, overwhelming miliary or pulmonary TB, severe or febrile illness, measles or other viral infections, Hodgkin's disease, sarcoidosis, live-virus vaccination, and immunosuppressive drugs. Anergy can be detected by the administration (via the Mantoux technique) of at least two additional delayed-type hypersensitivity antigens when testing with PPD. A person whose reaction to any of the three antigens measures 3 mm or more is not anergic.

Why Is Two-Step Testing Recommended?

Persons who have been infected with TB for many years may lose the ability to mount a positive reaction to tuberculin skin testing. However, a skin test will cause them to have positive reactions to subsequent tests, thus creating the possibility that the reader of the second test will identify the test subject as newly infected. To avoid that confusion, especially for individuals who are to be tested periodically, such as certain AOD employees, programs should employ a two-step testing procedure the first time they screen an individual for TB. Two-step testing calls for the administration of two tuberculin skin tests 1 to 3 weeks apart. If the first test is positive, the person is considered infected. If the first test is negative, a second test will be performed 1 to 3 weeks later. If the second test is positive, the person is probably infected; if it is negative, the person is probably not infected.

Who Should Be Screened?

High-risk persons should be screened for TB infection. These include:

- Persons with HIV infection
- Persons at risk for HIV
- Close contacts of persons with infectious TB
- Persons with certain medical conditions, such as diabetes mellitus, silicosis, or low body weight
- Persons who inject drugs
- Immigrants from areas where TB is common
- The medically underserved, the poor, and ethnic or racial minorities
- Residents of long-term care facilities
- The homeless.

Substance abuse programs should also screen employees who may be exposed to TB on the job or who would pose a danger to patients and other staff if they were to develop infectious TB.

Such employees should be screened upon employment and at intervals dictated by the risk of transmission in the facility (see chapter 6). Screened persons who test positive should be evaluated for active TB disease. If no active disease is present, infected persons at high risk for disease should be considered for preventive therapy.

Can the Progression From Infection to Active TB Be Prevented?

Persons who test positive for TB infection have a 10 percent lifetime chance of developing active TB disease. Preventive therapy with the anti-TB drug isoniazid or INH may prevent this from occurring. Clinical trials have shown that 6 to 12 months of preventive therapy with INH can reduce the risk of developing active TB disease by 69 to 90 percent.[15] The standard preventive treatment regimen consists of 6 months of treatment with INH.[16] (HIV-infected persons will be put on 12 months of INH preventive therapy.[17])

High-Priority Candidates for Preventive Therapy

Preventive therapy is not routine and is not indicated for all TB-infected persons. In particular, preventive therapy might not be indicated for persons at high risk for adverse reactions to INH, persons who cannot tolerate INH, persons who may have been exposed to a drug-resistant organism, pregnant women (unless they are in a high-risk group), and persons who are unlikely to follow the recommended regimen. The following are high-priority candidates for preventive therapy:

- Persons who are or may be HIV positive
- Close contacts of persons with infectious TB
- Persons whose chest x-ray suggests previous TB but who did not receive adequate treatment
- Persons who inject drugs
- Persons with certain medical conditions
- Persons infected within the preceding 2 years.

Others who should be evaluated for preventive therapy include persons who are under 35 years of age, have reacted to the tuberculin skin test with an induration of 10 or more millimeters, and who are foreign-born, poor, medically underserved, members of a minority group, homeless, or live in long-term care facilities. (Age is significant because those older than 35 years of age are at greater risk of developing INH-related hepatitis.)

What if a Person Has Been Exposed to a Drug-Resistant Organism?

High-risk patients on INH preventive therapy who are likely to have been exposed to an organism resistant to INH should receive preventive therapy with an alternative antituberculosis drug, e.g., rifampin or RIF. In cases where a patient's strain of *M. tuberculosis* is resistant to both INH and RIF, preventive therapy becomes more complicated. The CDC recommends that persons who are at high risk for developing TB disease, such as HIV-infected persons who may have been exposed to a multidrug-resistant strain of TB, take at least two antituberculosis drugs to which the infecting organism has shown susceptibility. For persons who are not at high risk

for developing TB disease, but who may have been exposed to a multidrug-resistant strain of TB, the CDC recommends either:

1. No preventive therapy but careful monitoring for signs of TB disease, or
2. A regimen of two antituberculosis drugs to which there is demonstrated susceptibility.

In making these recommendations, the CDC cautions that the efficacy of preventive therapy with drugs other than INH and RIF has not been established and that careful monitoring for signs of TB disease is suggested in such cases. An AOD program that is managing a patient who may have been exposed to multidrug-resistant TB should consult with an expert on multidrug-resistant TB for current recommendations regarding preventive therapy. Such experts can be identified through local or State public health departments.

Do Patients on Preventive Therapy Need To Be Monitored?

Patients on INH preventive therapy must be monitored monthly for adherence to the prescribed regimen and adverse reactions, especially symptoms or signs of hepatitis or neurotoxicity. (Patients should be advised to monitor themselves for the symptoms of hepatitis, which include nausea, vomiting, and loss of appetite.) Because of the importance of adherence to a successful outcome, the responsible clinician will not hesitate to raise adherence issues with his or her patients, count pills, or even order urine tests.

Directly observed preventive therapy will increase the chances of a successful treatment outcome. Directly observed therapy means that someone actually watches the patient take his or her prescribed medication. Although this work is usually performed by local or State public health workers, it can also be done by AOD staff.

With respect to possible adverse reactions, special precautions are recommended for persons who are older than 35 years of age, abuse alcohol, have a history of side-effects with INH, inject drugs, use medications that may contraindicate INH, have chronic liver problems, are pregnant, or have peripheral neuropathy or a condition associated with its development, such as diabetes mellitus.

Preventive Therapy in AOD Programs

AOD programs that wish to set up a TB preventive therapy program should be aware of the practical difficulties involved in administering preventive therapy. Among other things, programs should bear in mind:

- The importance of proper screening for TB
- The importance of correctly identifying appropriate candidates for preventive therapy
- The need to monitor for adherence and adverse reactions
- The importance of knowing whether the patient has been exposed to a drug- resistant strain of *M. tuberculosis*, and, if so, the susceptibility pattern of the source case's isolate.

The issues surrounding infection control and TB-related services within AOD programs are discussed in chapter 5.

Diagnosing Active TB Disease

TB infection and TB disease (or infectious TB) are not the same. Persons who are TB-infected but who do not have TB disease do not pose a danger of transmitting TB to others. Persons with active disease do pose such a danger. The best way, therefore, for a program to prevent the spread of TB within its facilities is to identify, isolate (or remove), and treat (or refer for treatment) patients and staff with active disease.

Who Should Be Evaluated?

Persons who are suspected of having TB, persons who have a positive reaction to tuberculin skin testing, and persons who present with symptoms that include a prolonged (3 or more weeks) cough, bloody sputum, chest pain, fever, night sweats, easy fatigability, loss of appetite, and weight loss should be evaluated for infectious pulmonary TB. (The index of suspicion will vary depending on the prevalence of TB in the surrounding community, the prevalence of TB in the facility itself, and individual or group risk factors.) An appropriate medical evaluation for TB disease (as opposed to infection) will include a medical history, physical examination, Mantoux tuberculin skin test, chest x-ray, and bacteriologic examination.

Medical History

A clinician will want to know whether a patient has a history of exposure to TB or a history of TB infection or disease. Where applicable, a clinician will want to know whether a prescribed regimen was adequate and whether it was followed, since inadequate or incomplete treatment may allow TB to recur and may result in drug-resistant forms of the illness. A proper history will inquire into risk factors that may increase the risk for active disease.

Physical Examination

A physical examination will not rule out or confirm TB. Nevertheless, it may yield valuable information that will help in treating the patient.

Tuberculin Skin Test

Tuberculin skin testing is discussed earlier in this chapter under "How Do We Screen for TB Infection?" It bears repeating that a negative skin test does not rule out TB, especially for persons who are immunosuppressed.

Chest X-Rays

Chest x-rays are the traditional method for detecting pulmonary TB disease in a person with a positive PPD and/or such symptoms as a persistent cough, fever, or chills. However, since a person with both HIV infection and active TB disease may have an apparently "normal" film,

chest x-rays are not necessarily definitive. Further laboratory examinations of a patient's sputum or other bodily specimens need to be conducted to confirm a diagnosis of TB disease. Chest x-rays can rule out pulmonary TB in a person with a positive skin test reaction but no symptoms of disease.

Bacteriologic Examination

Persons who are suspected of having pulmonary or laryngeal TB should have a series of three sputum specimens tested for tuberculosis by smear examination and culture. (Sputum is material that is brought up from the lungs; it is different from saliva.) A smear examination involves staining a smear of the patient's sputum with a dye designed to highlight the presence of tubercle bacilli when examined under a microscope. This test can produce a presumptive diagnosis of TB within 24 hours of the specimen's collection.

A smear examination cannot provide a definitive diagnosis of TB disease because the mycobacteria it locates in the sputum may be other than *M. tuberculosis*. To obtain a definitive diagnosis of TB disease, a laboratory culture of *M. tuberculosis* must be done. Such cultures are the most accurate method for detecting the presence of TB disease. Cultures can be done on a test subject's sputum, tissues, or bodily fluids. Cultures can be ready within 10 to 14 days of specimen collection. To help prevent transmission of disease, the CDC recommends that, where clinical signs and symptoms indicate the presence of disease, clinicians should not wait for the culture results to begin treatment.

In all cases, the *M. tuberculosis* isolate should also be tested for drug susceptibility. New tests make it possible to get susceptibility testing results within 5 to 7 days of culture inoculation. Other tests yield results within 2 to 6 weeks.

Treating Active TB Disease

What Is the Standard Regimen?

Treating active TB disease can take as little as 6 and as many as 24 months. For treatment to be effective, the TB organisms must be susceptible to the antituberculosis drugs used, the treatment must last long enough to be effective, and the patient must follow the prescribed regimen. The initial treatment regimen will usually consist of drugs, INH, RIF, pyrazinamide, and either ethambutol or streptomycin, and will last 6 months.[18] (Single drug regimens are not used because they can lead to the development of drug-resistant strains; multiple drugs reduce the chance of drug-resistance by complementing and reinforcing one another.) Assuming patient adherence and strain susceptibility, fully 95 percent of all immune-competent persons will emerge from treatment free of TB.

Directly Observed Therapy (DOT)

Because patient adherence is the single most important factor in the success of treatment (and because about 25 percent of all TB patients do not follow the prescribed treatment regimen), the CDC recommends that treatment be administered by means of directly observed therapy or DOT.

(This nonadherence is risky for both the individual concerned and for those in contact with him or her; it can lead to both TB and AOD relapse, the further transmission of TB, and the development of drug resistance.)

DOT means that a health care worker or public health employee will watch the patient to see that he or she takes the prescribed medication. As intrusive and paternalistic as this may seem, DOT has proved to be effective in reducing relapse and drug resistance. Further, it is cost-effective when used with an intermittent regimen, that is, a regimen that requires medication on a less than daily basis. Such regimens are easier to supervise than regimens that require daily medication.

For those programs wishing to employ DOT, the CDC advises that the DOT be carried out at a time and in a location that makes it as convenient as possible for the patient. In any event, all programs providing TB treatment (whether or not they use DOT) should promote adherence by doing the following:

- Developing individualized treatment plans
- Trying to provide culturally and linguistically appropriate outreach staff
- Educating patients about TB, TB treatment, and possible adverse reactions to treatment
- Using incentives
- Easing access to health and social services, where appropriate.

If necessary, the CDC recommends legal action to civilly commit nonadherent patients who are infectious, at risk for becoming infectious, or at risk for becoming drug-resistant.

Drug-Resistant TB Disease

A patient may acquire drug-resistant TB by developing drug-resistant organisms while being treated for drug-sensitive *M. tuberculosis* -- either because the drug therapy was inadequate or taken incorrectly -- or through primary infection, i.e., by being infected with a drug-resistant organism. The most common reason for the development of drug resistance is inadequate therapy. The most common drug resistance is to INH, one of the most effective anti-TB drugs.

Drug-resistant TB is treated through an individualized treatment plan based on the drug-susceptibility pattern of a patient's particular strain of *M. tuberculosis*. Because it can involve a variety of drugs, the treatment regimen for drug-resistant TB can be time-consuming, is often poorly tolerated by the patient, can result in unpleasant side effects, and may have an alarming failure rate.

In the early 1990s, the CDC investigated nine outbreaks of drug-resistant TB disease in hospitals and other institutional settings. The CDC's investigators found widespread multidrug-resistant or MDR TB disease among patients with HIV infection, a mortality rate as high as 72 to 89 percent, and a median interval of only 16 weeks from diagnosis to death.[19]

Monitoring Treatment for Active Disease

As with preventive therapy, treatment for TB disease must be monitored regularly for both adherence and adverse reactions. Patients should be instructed to look for signs or symptoms of adverse reactions and to report them immediately to health care workers or medical personnel. With respect to side effects, AOD programs should be aware that RIF or rifampin, one of the two key anti-tuberculosis drugs, accelerates the clearance of drugs metabolized by the liver. Thus, patients who are on methadone may require up to a 50 percent increase in their dosage of methadone. Lastly, patients need to be monitored to ensure that treatment is working and that they have not relapsed.

When May a Patient in Treatment for TB Return to the AOD Program?

To prevent the spread of TB in their facilities, AOD programs must identify, isolate (or remove), and treat (or refer for treatment), all patients and staff with active TB disease. Staff and patients with active disease may not return to the program until it is medically determined that they are not infectious. Fortunately, infectiousness in patients with TB disease declines quickly once effective therapy is implemented. TB-infected patients who have received adequate treatment for 2 to 3 weeks, have responded to the treatment, *and* have had three consecutive negative smear examinations from sputum taken on 3 separate days are no longer infectious. It will take about 2 months for most infectious TB patients to become noninfectious.

Endnotes

[1.] For more information about tuberculosis, see Centers for Disease Control and Prevention, U.S. Department of Health and Human Services*, Core Curriculum on Tuberculosis: What the Clinician Should Know* (3d ed. 1994) [hereinafter referred to as *Core Curriculum*], and Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Guidelines for preventing the transmission of Mycobacterium Tuberculosis in health-care facilities, 1994, *Morbidity and Mortality Weekly Report* 43 (Oct. 28, 1994) [hereinafter referred to as *Guidelines*], or contact your State or local health department TB program, your State or local American Lung Association, the American Thoracic Society, or the CDC Fax Information Service at (404) 332-4565.

[2.] *Core Curriculum, supra* note 1, at 11. There were slightly more than 25,000 new cases of TB reported in 1993. *Id*. A "case" of TB means a case of active or infectious disease, i.e., TB that can be transmitted to others. That one is infected with TB does not mean that one has active TB disease or is a threat to infect others. Persons who are infected with TB are not necessarily contagious. Only those whose infection develops into active disease will become infectious. The CDC estimates that there are between 10 to 15 million persons infected with TB in the United States. *Id*. at 13. Only a small percentage of those persons will go on to develop active TB disease and become contagious.

[3.] Outbreaks of multidrug-resistant TB have occurred in hospitals and correctional facilities.

Those episodes, which involved HIV-infected persons for the most part, resulted in the transmission of TB to health care workers. *Core Curriculum, supra* note 1, at 15. Several of the workers died.

[4.] Adherence to the recommended treatment regimen can hardly be taken for granted. The CDC estimates that approximately 25 percent of patients who start treatment for tuberculosis do not complete a recommended regimen within 12 months. *Id.*

[5.] CDC, *Core Curriculum, supra* note 1, at 3.

[6.] Of the new TB cases reported in 1993, 30 percent occurred in persons who were born and raised abroad. *Core Curriculum, supra* note 1, at 14.

[7.] Two-thirds of all TB cases in the United States occur in minorities. *Id*. With respect to the question of TB among racial and ethnic minorities, it should be noted that race is not a causal factor for TB. Listing racial and ethnic minorities here simply reflects the grim fact that many minority group members are poor and medically underserved. It is the lack of proper health care that conduces to the spread of disease among such populations.

[8.] Though we do not know the precise rate of TB infection among alcoholics and substance abusers, several studies indicate that it is high. One Baltimore study found that over 25 percent of the HIV-seronegative intravenous drug users studied were TB-infected. Neil Graham, et al., Prevalence of tuberculin positivity and skin test anergy in HIV-1-seropositive and seronegative intravenous drug users, *JAMA* 267:369, 370, 1992. In 1989, 20 to 25 percent of the patients in one New York City methadone maintenance treatment program had positive tuberculin skin test results. Peter A. Selwyn et al., A prospective study of the risk of tuberculosis among intravenous drug users with human immunodeficiency virus infection, *N Engl J Med* 320:545, 1989. An older but revealing study found that the rate of TB infection among hospitalized drug-dependent persons in New York City was 3,740 per 100,000, as opposed to only 86.7 per 100,000 among the general population. Lee B. Reichman et al., Drug dependence, a possible new risk factor for tuberculosis disease, *Archives Internal Med* 139:337, 338, 1979. And a 1990 survey of TB-infected persons in three U.S. cities revealed that nearly a quarter had been told that they had "a drinking problem." Jeffrey Glassroth et al., Why tuberculosis is not prevented, *Am Rev Respiratory Disease* 141:1236, 1990.

[9.] *Core Curriculum, supra* note 1, at 14.

[10.] *Core Curriculum, supra* note 1, at 7.

[11.] *Core Curriculum, supra* note 1, at 19.

[12.] The induration or tuberculin reaction is measured and recorded in millimeters. This is true whether or not the reaction is positive or negative, with a completely negative reaction being recorded as "0 mm."

[13.] CDC, *Guidelines, supra* note 1, at 61; CDC, *Core Curriculum, supra* note 1, at 21.

[14.] *Core Curriculum, supra* note 1, at 21.

[15.] *Core Curriculum, supra* note 1, at 36.

[16.] It is important to rule out TB disease prior to beginning preventive therapy with INH. When INH is used alone to treat TB disease -- which would be the case if a person with active TB disease were placed on INH preventive therapy by mistake -- resistance to INH is likely to develop. *Core Curriculum, supra* note 1, at 37.

[17.] Michael D. Iseman, Treatment of multidrug-resistant tuberculosis, *N Engl J Med* 329:784, 789, 1993; Centers for Disease Control, U.S. Department of Health and Human Services, The use of preventive therapy for tuberculosis infection in the United States: Recommendations of the Advisory Committee for Elimination of Tuberculosis, *Morbidity and Mortality Weekly Report* 39(RR-8): 9, 11, 1990.

[18.] CDC, *Core Curriculum, supra* note 1, at 44.

[19.] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Initial therapy for tuberculosis in the era of multidrug resistance: Recommendations of the Advisory Council for the Elimination of Tuberculosis, *Morbidity and Mortality Weekly Report* 42(RR-7): 1-2, 1993.

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The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
Treatment Improvement Protocol (TIP) Series 18

Chapter 4 -- AOD Programs and Public Health: Joining Together to Fight the Spread of TB

In 1992, Congress enacted a TB services mandate for all substance abuse programs that receive funding through the Substance Abuse Prevention and Treatment (SAPT) Block Grant.[1] That mandate requires those programs to make TB screening, evaluation, and followup routinely available for their patients. Department of Health and Human Services regulations require States to monitor, enforce, and facilitate program compliance with that mandate.[2] Complementing that mandate are State laws that require many AOD treatment providers to report cases of communicable disease, including TB, to local or State public health officials and to cooperate with them in patient followup. The purpose of both the mandate and State communicable disease reporting laws is to protect patients, program staff, and the public at large from the dangers of TB. Yet those laws will not accomplish that objective unless public health officials and AOD treatment providers cooperate with each other. As we will see below, there are many good reasons for -- and no significant impediments to -- such cooperation.

What Does the Law Require of Most AOD Programs?

The Federal TB Mandate

The Federal TB mandate requires AOD programs to provide or arrange for TB screening, evaluation, and followup for their patients. (The particular services that might be provided to discharge that obligation are discussed in chapter 5.) Depending on their resources, programs can provide those services directly or indirectly. Programs with limited resources may have to turn to public health officials for assistance in discharging those obligations.

State TB Control Laws

The control of communicable disease is generally a matter for the States. Toward that end, States typically require designated individuals or institutions -- so-called mandated reporters (including many AOD programs) -- to report cases of suspected or confirmed communicable disease to local or State public health agencies. The purpose of those laws is to enable public health officials to identify, locate, evaluate, treat, and monitor individuals and their close contacts who may have, or may have been exposed to, a communicable disease.

Case Reporting Requirements

Reporting laws vary from State to State. Some States require all AOD providers to report cases of communicable disease to public health. Others require only some providers, such as those who provide primary health care to their patients, to make such reports. Generally -- and this can create confidentiality problems for AOD providers -- reporters must identify both themselves and the individual who is the subject of the case report. The confidentiality problems raised by those requirements are compounded when States also demand information on the patient's substance abuse history, if any. The report is used by local or State public health officials to follow up on the patient's case, find contacts who may have infected or been infected by the patient, develop appropriate treatment plans, and monitor the treated individual's progress.[3]

Case and Contact Investigations

All States authorize or require their public health officials to investigate reported TB cases to confirm the case, ensure treatment, identify and locate contacts, and discover and treat new cases. However, where the case report is made by an AOD provider, or where the individual who is the subject of the report is a participant or resident in an AOD program, the success of subsequent case and contact investigations may depend on the program's willingness to cooperate with the public health investigators.

Followup for Treatment and Management

State TB control laws authorize public health officials to monitor individuals with TB disease to ensure that the prescribed treatment regimen is followed, that the regimen is having the desired effect, and that the patient is not suffering harmful side effects. To fulfill their duties properly, investigators may need access to the patient, the patient's records, or both.

How Can AOD Programs Avoid Violating Patient Confidentiality?

The Federal TB services mandate and State infectious disease reporting laws are vital to preventing the spread of TB in the AOD setting. However, AOD treatment programs in every State must comply with coordinate Federal laws that prohibit the disclosure of the identity of persons in alcohol or other drug abuse treatment. To the extent, then, that the TB laws and the TB services mandate hinge on the identification, location, evaluation, and monitoring of infectious or possibly infectious individuals who are in alcohol or drug treatment, they appear to conflict with the Federal confidentiality laws. Fortunately, that conflict is more apparent than real, since the Federal confidentiality laws contain mechanisms that make it possible for AOD providers to comply with both the TB services mandate and State TB reporting and followup laws without violating patient confidentiality.

Federal Confidentiality Laws

The Federal laws governing the confidentiality of AOD patient records are found in 42 U.S.C. § 290dd-2, a Federal statute, and in the regulations contained in volume 42 of the Code of Federal

Regulations, Part 2.[4] Enacted to encourage substance abusers to seek treatment without fear of disclosure or stigmatization, the Federal confidentiality regulations[5] essentially provide that *no federally assisted program that specializes in the treatment or diagnosis (or referral for treatment or diagnosis) of alcoholism or drug addiction may reveal the identity of anyone who has ever received or applied for its services*.[6] Before looking at the exceptions to that rule, let us take a closer look at its elements.

What Is a Program?

A program is a federally assisted entity that provides (and holds itself out as providing) individualized drug or alcohol abuse diagnosis, treatment, or referral for treatment.[7] A program may be an individual, e.g., a psychologist or counselor, or an organization. The regulations do not reach individuals or organizations that do not provide, and hold themselves out as providing, such specialized services.

What Does It Mean To Be Federally Assisted?

A program is federally assisted, and therefore covered by the regulations, if it receives Federal funds in any form, even if the funds do not directly pay for alcohol or drug abuse services. A program is federally assisted if it receives reimbursements from Medicaid or Medicare, is exempt from Federal taxation, is licensed or certified by the Federal Government, for example, to dispense methadone, or receives State or local funds that can be traced to Federal funds.[8]

Diagnosis, Treatment, or Referral

The regulations apply to programs that diagnose, treat, or make referrals for treatment for drug addiction or alcoholism. A program need not provide all three services to be covered by the regulations. The diagnosis of alcoholism or addiction need not be made by a physician in order for the regulations to apply. Similarly, the regulations apply even if the treatment itself is provided by a non-physician.

Who Is a Patient?

The regulations protect any person who has applied for, participated in, or received an interview, counseling, or any other service from a federally assisted alcohol or drug abuse program.[9] The regulations protect the records and identities of current, former, would-be, and even deceased patients.[10]

What Is a Disclosure?

The regulations prohibit AOD programs from disclosing the identities of the individuals they serve or have served. A "disclosure" is a communication that identifies an individual as having participated in, participating in, or seeking to participate in drug or alcohol abuse treatment.[11] Both explicit and implicit disclosures are prohibited.[12] However, a communication that does not reveal an individual's status as a patient in alcohol or drug abuse treatment is not a "disclosure"

for purposes of the regulations. Thus, a communication that reveals a person's name and address is not a disclosure so long as it does not reveal that the person is in AOD treatment. What is protected is not the person's identity per se, but his or her identity as a person who is dependent on alcohol or drugs.

Exceptions to the Regulations

Despite their strictness, the Federal AOD confidentiality regulations contain a number of exceptions that allow AOD programs to, first, cooperate with public health officials in providing TB services to their patients, and, second, comply with virtually all State TB reporting, disclosure, and followup requirements. Specifically, disclosures are permitted:

1. Where authorized by patient consent
2. Under a qualified service organization agreement
3. To report a medical emergency
4. Where they do not reveal that the patient is in treatment for alcohol or drug abuse
5. To report a crime on the program's premises
6. To report child abuse or neglect
7. Where authorized by a court order
8. For an audit or evaluation
9. For research
10. For purposes of internal program communications.

The following discussion will focus on the four exceptions that would be most useful to AOD programs in their interactions with public health: patient consent, non-patient identifying disclosures, qualified service organization agreements, and medical emergencies.

Patient Consent

The best way, both legally and ethically, for an AOD provider to comply with State-mandated TB reporting requirements and to cooperate with State or local public health officials in providing TB services to patients -- without violating the Federal confidentiality regulations -- is to secure patient consents to needed disclosures. A valid consent allows a program to disclose almost anything about a patient.[13] To be valid, however, a consent must be in writing and must include all of the following elements:

- The name of the program authorized to make the disclosure
- The name of the person or organization that is authorized to receive the information
- The name of the patient who is the subject of the disclosure
- The purpose of the disclosure
- A description of the information to be disclosed (which must conform as narrowly as possible to the purpose of the disclosure)
- A revocation provision which states that the patient may revoke his or her consent at any time except to the extent that action already has been taken in reliance upon the consent[14]

- An expiration date (or the specification of an event that will cause the consent to expire)
- The date
- The patient's signature.

A consent that does not include each of the foregoing elements, e.g., a general medical records release, is invalid for purposes of disclosing AOD information. (A sample consent form is included in appendix C.)

A disclosure made pursuant to a consent -- whether oral or written -- must be accompanied or followed by a written notice warning the recipient that the information being disclosed is protected by Federal law and may not be redisclosed except as allowed by another consent or pursuant to an exception in the Federal regulations. (The necessary redisclosure prohibition notice is included in appendix C.)

In the public health context, a properly executed consent can (1) authorize the patient's AOD program to comply with State-mandated TB reporting and followup requirements, (2) permit the program to communicate with the appropriate public health officials on an ongoing basis for the purpose of treating or coordinating the patient's TB care, (3) allow the recipients to redisclose AOD patient-identifying information, if necessary, and (4) permit the program to cooperate with public health officials should the latter -- as is usually the case -- wish to locate, examine, counsel, treat, or monitor the patient.

As useful as patient consents are, however, they are not without their limits. Programs that elect to rely on them for purposes of complying with State TB control laws should bear in mind that (1) patients can always refuse to sign them, and (2) patients can generally revoke them at will. Also, no AOD patient-identifying information that has been disclosed with the patient's consent may be used to conduct any criminal investigation or to substantiate any criminal charges against a patient, unless a special court order authorizing its use for that purpose has been obtained in compliance with the confidentiality laws.[15]

To avert the problems that can arise where a patient refuses to sign a needed consent, or revokes an earlier one, a program can elect, depending on State law, to condition participation in treatment on a patient's willingness to consent to certain disclosures, including TB-related disclosures. (That would not violate the Federal confidentiality laws.) In deciding whether to pursue that tactic, a program will have to weigh its obligations to the patient against its obligation to prevent the transmission of TB in its facilities. The decision may come down to choosing between the program's obligations to the one and its obligations to the many, i.e., everyone else in the program.

In any event, patient consent is the recommended mechanism for releasing confidential AOD information. To protect patients who consent to the release of confidential information to public health officials, AOD treatment providers should:

- Explain to patients that a consent to certain disclosures can facilitate both AOD and TB treatment
- Emphasize that the program will disclose only information that is relevant to treatment

- Reassure patients about the continuing confidentiality of the released information
- Ensure that AOD and public health officials who are provided with confidential AOD information thoroughly understand the importance of confidentiality
- Respect the patient's right to refuse or withdraw consent
- Develop strict guidelines for dealing with breaches of confidentiality.

Communications That Do Not Disclose AOD Patient-Identifying Information

Some AOD programs may be able to comply with their State-mandated TB reporting obligations by making mandated TB case reports without the disclosure of AOD patient-identifying information. Under the non-patient-identifying information exception to the regulations, a program may disclose a patient's name and whereabouts as long as it does not reveal that the patient has been in or has applied for substance abuse treatment. What the regulations protect is not the patient's identity per se, but his or her identity as a person who has been treated, is being treated, or has asked to be treated for drug or alcohol abuse.

However, State TB control laws regularly require disclosure of the addresses of both the individual whose TB case is being reported and the person or institution making the report. For this reason, resort to the non-patient-identifying exception is feasible only where the patient is in outpatient (as opposed to residential) treatment or where the program can make the necessary report without revealing the nature of its services.

Where the relevant law requires that a patient's address be disclosed, and the patient's address is also the program's address, and disclosure of the program's address would reveal the nature of the program, one cannot rely on that exception without revealing that the patient who is the subject of the report has a substance abuse problem. But where the patient is not in residential treatment, and where a program need not reveal its address or can use an address that does not reveal its identity as a treatment program (e.g., where the program is part of a general hospital), the program can make the required report without violating the regulations. Unlike the consent exception, the non-patient-identifying exception allows a program to cooperate with public health officials in their followup activities, i.e., examining, investigating, counseling, treating, monitoring, or contact tracing, only to the extent that the patient's status in AOD treatment is not disclosed.

Qualified Service Organization Agreements (QSOAs)

AOD treatment providers must frequently share patient-identifying information with outsiders who provide services for them or their patients, such as dentists, accountants, and laboratories. In order to do that without violating patient confidentiality, treatment providers must either secure patient consents or conclude what is known as a qualified service organization agreement (QSOA) with the outside service provider.[16]

A QSOA is a contract -- a rather simple one (see appendix C) -- that permits an AOD treatment provider to share patient-identifying information with an outside service provider where:

1. The outside service provider needs that information to provide services for the program or its patients, and
2. The outside service provider agrees not to redisclose that information.

In effect, a QSOA extends the orbit of the AOD provider to include the services of the outside agency. Consequently, patient consent is not required for disclosures made between the AOD program and the outside service provider under such agreements. Nor is the treatment program required, under the regulations, to disclose to its patients that it is or may become a party to such agreements. Although the Federal confidentiality laws do not require a treatment program to disclose to its patients that it is or may become a party to such agreements, programs may be obliged to do so by State law requirements or may choose to do so out of ethical or therapeutic considerations.[17]

Reporting communicable diseases under a QSOA. An AOD treatment provider may comply with State laws that require the reporting of cases of communicable disease by entering a QSOA with an outside service provider, such as a laboratory or private physician. The outside service provider would make the necessary reports without disclosing that the subject of the report is a participant in a substance abuse treatment program. Among other things, the outside service provider could report the patient's name, address, social security number, date of birth, communicable disease diagnosis, and other objective data without violating the Federal confidentiality laws.

Providing TB services through a QSOA. An AOD program that does not have the resources to provide the full array of TB-related services to its patients (see chapter 5) could arrange to have those services provided to its patients through a QSOA with a private physician or local public health officials. A QSOA with local public health officials would be superior to one with a private physician, because it would give public health officials relatively free access to program patients for followup treatment, monitoring, and contact tracing.[18]

Medical Emergencies

The confidentiality regulations allow programs to disclose patient-identifying information, even without a patient's consent, to public or private medical personnel who "have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention."[19] This exception does not offer programs a blanket authorization to report all their patients' suspected or confirmed TB cases to public health officials (or to communicate freely with those officials in the course of following up reported cases). This is because the medical emergency exception can only be invoked on a case-by-case basis, after a program has determined that the circumstances justifying a disclosure of information about a particular patient exist in that case. However, the exception will allow programs in many States to communicate with public health personnel about the TB cases of most urgent concern to everyone: those where an AOD patient is known or suspected to have infectious TB but is not known to be receiving TB treatment.

A disclosure under the medical emergency exception is justified only when a program determines that a patient's condition is one that both poses an immediate threat to his or her

health or to that of others, and requires immediate medical intervention. Because TB can be transmitted by casual contact (that is, the sharing of air space), because infectious TB poses an immediate health threat requiring immediate medical intervention, and because there is generally no way to determine whether an individual is definitely infectious without time-consuming testing, this requirement would be met in a case where a program has reason to suspect that a patient or applicant has infectious TB that needs to be -- but is not being -- diagnosed or treated immediately.

Disclosures under this exception can be made only to "medical personnel" who need information about a patient in order to treat the condition requiring immediate medical intervention (or ensure that someone else does so). Although the confidentiality regulations do not specifically define the "medical personnel" to whom such disclosures may be made under this exception, a common sense reading of this term would include public health officials in States where the public health authorities are either directly involved in diagnosing or treating reported cases of TB or have the authority to arrange for the immediate medical intervention that is needed in such cases.

Although the medical emergency exception to the confidentiality laws would allow AOD treatment providers to report cases or suspected cases of active TB in the circumstances described above, it would not allow them to cooperate with public health officials for purposes of patient followup and contact tracing.

When a TB report is made under this exception, the reporter must document the circumstances surrounding the disclosure, including the medical personnel to whom the disclosure was made.[20]

Cooperating With Public Health Officials

If AOD treatment providers are to comply with State communicable disease reporting laws and the Federal TB services mandate, they will have to cooperate with various outsiders, including public health officials. Invoking the patient consent and QSOA exceptions to the confidentiality laws would facilitate such cooperation.

How Collaboration Benefits All Concerned Parties

Cooperation between the AOD and public health fields would benefit AOD patients with TB, AOD administrators and staff, and the public at large.

Cooperation Would Benefit Public Health

Cooperation between the public health and AOD fields in the effort to prevent the transmission of TB in AOD facilities would have the following benefits:

1. Make it easier to identify cases of TB
2. Promote adherence to treatment in a troubled population
3. Facilitate the provision of directly observed therapy
4. Facilitate followup, including contact investigations
5. Make it easier to monitor patients on preventive therapy or in treatment.

Cooperation Would Benefit AOD Programs

Collaboration between the AOD and public health fields would also benefit AOD programs by:

1. Contributing to improved patient health (an important element in the recovery process)
2. Making it easier for programs to develop appropriate and effective TB infection control protocols
3. Making available relatively low cost TB evaluation, preventive therapy, and treatment for AOD patients
4. Linking the public health field into the AOD referral network.

Common Benefits

Collaboration would result in common benefits. These would include (1) improved services for patients who suffer from both communicable disease and addiction, (2) efficient use of scarce resources, (3) reduced risk for TB for patients, staff, and others, and (4) greater compliance with Federal, State, and local mandates regarding TB screening, evaluation, and treatment. Even if the Federal TB services mandate were eliminated, the impact of the TB epidemic on those served by AOD programs is so great that collaboration between AOD programs and public health officials would remain crucial and mutually beneficial.

Facilitating Collaboration

Despite its apparent benefits, collaboration between the public health and AOD fields will not always be easy to achieve. This is in part because some AOD treatment programs believe that collaboration with public health would compromise their independence or jeopardize patient confidentiality. On the other hand, some in the public health field think that AOD administrators and counselors get in the way of efforts to combat communicable diseases. Accordingly, if the AOD and public health fields are to collaborate successfully, they will have to (1) educate one another about their respective objectives, obligations, and cultures, (2) make clear what it is that they can do for each other, (3) clarify boundaries and identify mutually beneficial mechanisms for crossing those boundaries, and (4) be sure to remind one another that, in the end, they share a profound commitment to health.

Questions of Turf, Money, and Trust

Mistaken notions about what is permitted by the confidentiality regulations are not the only impediment to collaboration between the AOD treatment and public health fields. Political and financial concerns can all too easily conduce to suspicion and distrust between individuals who otherwise have much in common.

Whose Turf Is It?

The public health and AOD fields must be clear about their respective responsibilities regarding TB in the AOD setting. They must be open and frank about what each can and cannot do in the

effort to prevent TB. Concerns that the one is not doing enough, or that the other is preventing access to patients, must be addressed and overcome. Misunderstandings over turf, respective responsibilities, and cooperation can result in the loss of patients to both systems.

Money

Inadequate funding can be an obstacle to collaboration. TB challenges the already stretched resources of both the AOD and public health fields. Collaboration offers the advantages of saving scarce resources and shoring up everyone's bottom line. To facilitate collaboration, AOD providers and public health agencies should cooperate in identifying resources and promoting efficiency in the implementation of TB protocols and the provision of TB services.

Patient Mistrust

Patient mistrust can impede collaboration between public health and AOD agencies and can lead substance abusers to walk away from treatment. By way of reassuring their patients, AOD treatment providers should therefore strive to:

- Address patient concerns about sanctions related to TB services
- Address concerns about the availability of needed services
- Address concerns about confidentiality
- Change any negative perceptions that AOD counselors may have of public health, since counselors can influence patient attitudes and perceptions
- Use outreach programs and drop-in centers to reach difficult populations and develop patient trust
- Make it clear to undocumented aliens that health officials will not contact immigration authorities or investigate their immigration status.

Moving Toward Partnership

While some degree of cooperation already exists between many AOD and public health agencies, the ultimate goal of both AOD and public health should be a genuine partnership. Partnership means that both agencies will share responsibilities and work towards mutually agreed upon goals. To promote the possibilities of partnership, AOD and public health agencies should:

- Share and exchange training (for example, AOD providers can train public health officials on alcoholism and substance abuse issues, and public health officials can provide infectious disease education to AOD counselors)
- Develop mutually beneficial propaganda, such as brochures and posters aimed at shared patients
- Identify which collaborative efforts work and which need improvement
- Encourage communication to lessen interagency misunderstanding.

Cooperative Agreements

One way of fostering partnership between the AOD and public health fields would be to develop interagency agreements that would set out in detail the roles and responsibilities of each in the screening, treatment, and followup of AOD patients. Clear and practical agreements can facilitate patient access to TB services and improve patient outcomes. Such agreements should address:

- **Cross-training:** Training for public health officials should address issues relevant to the AOD population. Training for substance abuse providers must focus on the origins, identification, and treatment of communicable diseases. Where appropriate, the parties might wish to collaborate on appropriate training materials.
- **Risk assessment surveys:** Risk assessments are critical to the control of TB infection in AOD facilities. However, those assessments cannot be made without the assistance of properly trained experts. Public health officials can provide the necessary expertise to AOD providers.
- **Record keeping**: Record keeping is vital to the control of TB in the AOD setting. Public health officials can assist AOD providers to develop appropriate record keeping procedures. AOD providers can help familiarize public health officials with the relevant confidentiality issues.
- **Review of agreements:** Cooperative and partnership agreements must be reviewed periodically for effectiveness.
- **Contacts:** Each party to a cooperative or partnership agreement must have a list of key contacts in the other party's organization.
- **State-local public health collaboration:** State and local authorities should develop top-to-bottom strategies for cooperating with AOD providers and providing effective TB services.

Who Else Might Be Included in a Cooperation Agreement?

AOD and public health providers agree that TB services for AOD patients could be enhanced by cooperation between all the agencies and institutions that deal with AOD abusers. These include departments of corrections, HIV/AIDS service providers, social service agencies, immigration services groups, charitable organizations, mental health agencies, Indian Health Services, tribal organizations and institutions, housing authorities, advocates for the homeless, community health centers, migrant health programs, public hospitals, and others who specialize in the provision of services to special care populations. Successful treatment of shared patients will depend on a comprehensive response from the relevant agencies.

Efforts in Four States To Meet the TB Mandate

Some States are promoting partnerships between AOD providers and public health. Those partnerships seek to (1) integrate TB screening, counseling, and medical services with substance abuse treatment, and (2) facilitate TB reporting, followup, and monitoring. Following is an overview of activities in Arkansas, Massachusetts, Nevada, and New York.

Arkansas

In January, 1993, the Arkansas Department of Health's (ADH) Bureau of Alcohol and Drug Abuse Prevention (ADAP) and Division of Tuberculosis entered into a memorandum of agreement (MOA) that outlined areas of collaboration with respect to drug abusers infected with or at risk for TB.

TB screening, counseling, and treatment services in Arkansas AOD programs. Under the

MOA, ADH staff train designated staff persons from each residential substance abuse treatment program to administer tuberculin skin tests to patients and interpret the results. Patients are to be screened for TB upon admission and annually thereafter. PPD-positive patients are referred to local health units for followup testing and evaluation. Substance abuse treatment programs provide on-site directly observed therapy (DOT) to ensure patient compliance with TB medication regimens. In addition, the MOA calls for the annual TB testing of treatment program staff.

Recognizing the connection between HIV and TB and the increased dangers that TB poses for immunocompromised individuals, the MOA encourages HIV testing and counseling for patients in treatment, especially for those who are PPD positive.

Infection control in Arkansas AOD programs. The MOA outlines steps to be taken by ADH and ADAP to install germicidal ultraviolet (UV) lights in all residential treatment programs. ADH staff survey program rooms for size, ceiling height, and patient distribution. The program then purchases the recommended light fixtures and bulbs. ADH staff install them. ADH also teaches programs how to clean and maintain the lights. Programs must keep records documenting the proper care and replacement of UV lights to ensure their continued effectiveness. UV lights are now being installed in all residential treatment facilities.

Training. In addition to the training outlined above, ADH gives ADAP staff and AOD providers regular training regarding TB and HIV issues. In exchange, the MOA calls for ADAP to train ADH on substance abuse issues, particularly those related to injection drug use. ADAP also conducts regional meetings to inform ADH staff about the services ADAP provides and to establish links to medical care for patients.

Ongoing collaboration. ADH's Division of Tuberculosis staff and ADAP's Infectious Disease Coordinator meet on a quarterly basis to share information and to develop primary care linkages and referral arrangements for patients in drug and alcohol abuse treatment. ADAP and ADH also conduct joint visits to treatment facilities to monitor the effectiveness of the State's TB control efforts. Finally, ADH and ADAP providers have entered QSOAs for the purposes of reporting TB-related information and coordinating TB services within the bounds of the Federal confidentiality regulations.

Massachusetts

Massachusetts has taken a number of steps to prevent the transmission of TB in AOD facilities, including the following:

- In 1990, the Division of Tuberculosis Control (the Division) and the Bureau of Substance Abuse Services (BSAS) collaborated on a policy statement for TB control in AOD facilities. (See appendix D.) That statement outlines procedures for TB screening, followup, reporting, and monitoring of treatment.
- In 1991-92, pamphlets were produced on HIV and TB (see appendix E) and on the connection between substance abuse and sexually transmitted diseases, hepatitis B, TB, and HIV/AIDS (see appendix F).
- In 1993, the Division and BSAS collaborated with CSAT to provide a 2-day training for substance abuse treatment providers and communicable disease staff.
- Since 1989, the Division has received money from the Centers for Disease Control and Prevention (CDC) to provide TB screening, followup, and directly observed preventive therapy at seven methadone maintenance treatment programs.
- Massachusetts has drafted a consent form for release of confidential information for AOD patients.
- Other activities include educating AOD providers about TB, STDs, and HIV, visits by Division staff to AOD providers, joint mailings, and the creation of links between TB and STD clinics.

Nevada

Nevada's efforts to provide TB services to substance abusers were a direct response to the Federal TB services mandate. In December 1992, Bureau of Alcohol and Drug Abuse representatives and Clark County public health officials met to explore ways of integrating TB and AOD services. That meeting led to the establishment of a pilot project to enhance TB services in Clark County substance abuse treatment programs. The project was funded by a grant from the Center for Substance Abuse Treatment (CSAT).

TB screening, counseling, and treatment services in Nevada AOD programs. Under the pilot project, a Clark County Health Department nurse travels to publicly funded alcohol and drug treatment centers to administer PPD tests and to make referrals for followup x-rays and treatment. Patients with positive PPD results are transported to local clinics for chest x-rays. The nurse also works closely with the treatment programs to ensure proper case management.

Training. Nevada cross-trains AOD counselors and public health staff to promote mutual understanding and an appreciation of each field's concerns and obligations.

Ongoing collaboration. Discussions are underway to replicate Clark County's model elsewhere in the State.

New York.

In light of the incidence of TB and HIV/AIDS among substance abusers in New York, the New York State Office of Alcoholism and Substance Abuse Services (OASAS) has pursued policies that emphasize early detection, on-site provision of DOT, environmental control, and collaboration with public health officials to reduce the risk of transmission of TB in AOD facilities.

TB screening, counseling, and treatment services in New York AOD programs. In 1992, OASAS issued two Administrative Bulletins that outlined the minimum TB control procedures for alcoholism and substance abuse treatment programs in New York State. Those directives recommended:

1. Incorporating TB screening into the admissions process of all treatment programs
2. Providing followup chest x-rays and anergy panel testing, where indicated
3. Annual retesting of PPD negative patients.

OASAS also recommends testing all staff at least once a year, screening staff at highest risk every 6 months, and testing new employees upon hiring.

OASAS has developed several initiatives to link patients with TB treatment. In New York City, OASAS, the New York City Department of Health (NYC DOH) and the Committee of Methadone Program Administrators match the names of persons on the central methadone registry with those on the TB registry. Under this arrangement, NYC DOH makes available to the private, nonprofit agency that maintains the methadone registry a list of persons documented as either having active TB or having failed to adhere to treatment. The nonprofit agency notifies the appropriate methadone program whenever there is a match. The methadone program then asks the patient for permission to contact the NYC DOH to arrange for followup services. This arrangement has identified more than 300 methadone patients who have active TB or who failed to complete TB treatment.

OASAS has also collaborated with the New York State Department of Health to enable several New York City methadone maintenance treatment programs (MMTPs) to provide on-site DOT to their patients. A CDC grant, administered in cooperation with the NYC DOH and the New York State Department of Health/AIDS Institute, has enabled eight MMTPs and one therapeutic community in New York City to develop on-site directly observed preventive therapy for patients with TB infection. The grant allows Disease Preventive Specialists to perform on-site PPD tests, interpret the results, conduct or arrange followup testing, and provide directly observed preventive therapy. Disease Preventive Specialists also screen for side effects and anergic reactions.

TB environmental control in New York AOD programs. OASAS has assessed the TB environmental control needs of 36 alcoholism and substance abuse treatment facilities throughout New York State as part of a program to ensure a safe environment in MMTPs and Alcoholism Crisis Centers. The program is intended to provide UV lights and improve ventilation in those facilities. To qualify for the program, a program must have a comprehensive

TB program in place, including patient and staff screening, and formal linkages with local hospitals to provide x-rays and dispense TB medication. OASAS hopes to expand the program to other facilities.

Training. OASAS has issued bulletins to providers which include basic educational information on TB. A TB control plan is a required part of the providers' HIV Program Plan, which is required by regulation of all OASAS-licensed drug treatment programs.

Ongoing collaboration. OASAS has discussed replicating the cross-referencing of TB and methadone registries with the Health Department in Westchester County. OASAS has had discussions with the Monroe County Health Department regarding the possibility of the latter's conducting on-site testing in the county's AOD programs.

Endnotes

[1.] Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, PL 102-321, § 1924(a)(1), 106 Stat. 391 (1992), 42 U.S.C. § 300x-24(a)(1) (1994). The SAPT Block Grant is the major source of Federal financing for substance abuse treatment programs. The Grant is administered by the Center for Substance Abuse Treatment (CSAT) and is funneled to treatment programs through the primary substance abuse agency in each state. In addition to providing TB services for patients, AOD programs must also provide appropriate referrals for applicants in need of TB evaluation or treatment who are turned away from AOD treatment for lack of space. Obviously, AOD providers will want to make such referrals for anyone who needs them, not just those who have been turned down for lack of space.

[2.] The regulations require State substance abuse agencies, departments of health, and medical directors for substance abuse services to cooperate in developing procedures to ensure that programs provide the mandated services, implement infection control procedures, report cases of TB to local or State public health departments, and provide case management for those in need of TB services. To facilitate the provision of TB services, Single State Agencies are expected to cooperate with local tuberculosis control officers to create the necessary linkages between AOD and other health care providers, 45 C.F.R. § 96.127(b).

[3.] For a survey and discussion of TB reporting and control laws in the 50 States, see Centers for Disease Control, U.S. Department of Health and Human Services, Tuberculosis control laws -- United States, 1993, *Morbidity and Mortality Weekly Report:* 42(RR-15):1, 3, 1993; and Lawrence O. Gostin, Controlling the resurgent tuberculosis epidemic, *JAMA* 269:255, 1993.

[4.] The regulations implementing the Federal AOD confidentiality law were revised by the Department of Health and Human Services in 1987, and more recently on May 5, 1995 (60 *Federal Register* 22296). For a thorough discussion of the regulations, see Legal Action Center, *Confidentiality: A Guide to the Federal Law and Regulations*, rev. ed. 1995.

[5.] When we speak of the Federal regulations, we are referring to the regulations in the Code of

Federal Regulations; the actual statute is rarely referred to.

[6.]The prohibition on unauthorized disclosure applies whether or not the person seeking information already has the information, has other means of obtaining it, enjoys official status, has obtained a subpoena or warrant, or is authorized by State law. 42 C.F.R. §§ 2.13(b) and 2.20. State laws permitting or requiring disclosures that are prohibited by the Federal regulations are invalid.

[7.]42 C.F.R. §§ 2.11, 2.12(a)(1)(ii). The 1995 revisions to the regulations' definition of covered "program" in §§ 2.11 and 2.12(e)(1), which became effective June 5, 1995, are set forth at 60 *Federal Register* 22296-22297, May 5, 1995.

[8.]42 C.F.R. § 2.12(b).

[9.]The regulations require programs to notify patients of the existence of the Federal confidentiality laws and regulations and to give them a written summary of the confidentiality provisions. The notice and summary should be provided at admission or "as soon thereafter as the patient is capable of rational communication." 42 C.F.R. § 2.22(a). The regulations list five items that must be included in the written summary and a sample notice: (1) a description of the few circumstances in which disclosures can be made without consent; (2) a statement that violation of the regulations is a reportable crime; (3) a warning that information can be released if the patient commits or threatens a crime on program premises or against program personnel; (4) a notice that the program must report suspected child abuse or neglect; and (5) a citation to the law and regulations. *Id.* at § 2.22(b). The regulations contain a sample notice at § 2.22(d).

[10.]42 C.F.R. §§ 2.11, 2.15(b).

[11.]42 C.F.R. §§ 2.11, 2.12(a)(1)(I).

[12.]42 C.F.R. § 2.13(c).

[13.]42 C.F.R. §§ 2.31, 2.33. A consent may authorize the recipient to redisclose patient-identifying information.

[14.]Consents for persons mandated into treatment through the criminal justice system may be made irrevocable for periods of time, depending on the State law (42 C.F.R. § 2.35).

[15.]42 U.S.C. § 290dd-2_; 42 C.F.R. §§ 2.12(d)(1) and 2.65.

[16.]42 C.F.R. §§ 2.11, 2.12(c)(4). According to the U.S. Department of Health and Human Services (which revised the Federal confidentiality regulations in 1987), treatment programs can enter QSOAs with a broad array of service providers, though generally not with one another. Generally, QSOAS are permitted between treatment programs only where the service provided by the second program does not pertain to drug or alcohol abuse education, training,

treatment, rehabilitation, or research. Under no circumstances may an AOD treatment provider enter a QSOA with a law enforcement agency.

[17.] Although the confidentiality regulations do not require patient consent to enter a QSOA with an outside service provider, many providers believe that it is unethical not to inform clients of the existence of such agreements. Patient notification of the existence of QSOAS reduces surprise and protects the therapeutic relationship.

[18.] If the outside agency is a laboratory, it can report its analyses to public health officials. As a laboratory, however, it cannot follow up on the patients whose test results it reported, i.e., it cannot treat them. But if the outside agency is a health care provider, it can not only make the necessary reports to public health, it can also provide treatment and followup to the patient in question.

[19.] 42 C.F.R. § 2.51.

[20.] 42 C.F.R. § 2.51(c).

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Chapter 5 -- Providing TB-Related Services to Patients

The patients and staff of certain AOD programs are at increased risk for TB exposure, infection, and disease. To prevent the spread of TB, programs must screen both patients and staff, make sure that individuals who pose a threat of transmitting TB to others are isolated or removed (at least until the threat of transmission is eliminated), provide appropriate referrals for evaluation and treatment, provide appropriate followup (directly or indirectly), and educate all concerned regarding the facts about TB. In discharging these obligations, AOD programs may not disregard either the confidentiality or civil rights of patients or staff.

Must AOD Programs Provide TB Services?

Federal law and regulations require AOD providers who receive Substance Abuse Prevention and Treatment (SAPT) Block Grant monies to implement TB infection control procedures and make TB services available to both patients and applicants for AOD services. The tuberculous services requirements are contained in section 1924(a) of the Public Health Service (PHS) Act. The purpose of the TB services mandate is to prevent the transmission of TB in the treatment setting and to ensure that AOD patients get access to screening, evaluation, treatment, and followup for TB. Section 1924(c) of the PHS Act and 45 C.F.R. § 96.137 provide that the block grant may be used to pay for such services although, as stated in the regulations, the block grant funds may be used only as the "payment of last resort." However, since most AOD programs cannot provide on-site medical services for their patients (or would-be patients), the mandate can be satisfied only if such AOD providers collaborate with public health or other health care providers. Under the circumstances, AOD programs might wish to view the mandate as an opportunity to explore and develop mutually beneficial partnerships with State and local public health departments, partnerships that can serve as models for dealing with other issues of mutual interest. In pursuing such partnerships and seeking to comply with the Federal TB services mandate, however, AOD programs must be careful not to discriminate unlawfully against persons who are, have been, or are suspected of being infected with TB. Federal disability law prohibits discriminating against persons with TB or a history of TB who are not contagious, that is, who present no threat of transmitting infection to others.[1]

Can AOD Programs Exclude Patients or Staff With TB?

AOD programs may not discriminate against persons who have, have had, or are suspected of having TB unless such persons pose a significant risk to the health or safety of others.

Are Persons with TB Protected by Federal Disability Law?

The Federal Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 (ADA) protect individuals from disability-based discrimination.[2] Virtually all AOD programs are subject to one or both of those laws. Under those statutes, AOD providers:

- May not exclude from treatment a qualified individual -- that is, an individual who meets the essential eligibility requirements of the program -- on the basis of a disability
- May not establish eligibility criteria that screen out or tend to screen out the disabled -- unless the eligibility criteria are necessary for the provision of the services the program offers or are necessary for the safe operation of the program
- May not provide services to a disabled person that are different, separate, or not equal to those that are offered to others -- unless doing so is necessary to provide the individual with services that are as effective as those provided to others
- May not engage in acts or practices that discriminate against the disabled.

Those laws apply to persons with TB.

What About Persons with Infectious TB?

Where a person -- whether or not he or she is disabled -- poses a "significant risk" to the health or safety of others, and that risk cannot be eliminated by a reasonable accommodation, he or she may be found not to "qualify" for participation in a given activity, including participation or employment in an AOD program.

Who Poses a "Significant Risk"?

The determination of whether a given individual poses a significant risk to the health or safety of others must be made on a case-by-case basis. A person who is infected with TB but who is not infectious poses no health or safety risk to others. The same may not be said of an individual who has active TB and is contagious. Individuals who are contagious pose a significant risk to the health and safety of other AOD patients and staff. Such individuals must be detected, isolated, and treated as soon as possible. Accordingly, the responsible provider will evaluate and treat the person (assuming it has the resources to evaluate and treat active TB disease) or refer him or her for appropriate evaluation and treatment.

Can a "Reasonable Accommodation" Be Made?

In determining whether a given individual poses a "significant risk" to the health or safety of others because of his or her infectiousness, the provider must also determine whether there are not "reasonable accommodations" (or modifications) that might be made to eliminate the risk of transmission. An accommodation is reasonable as long as it eliminates the risk of transmission without imposing an undue burden on the provider or requiring fundamental alterations in program services.

Thus, if a residential program already offers primary care services to its patients and has in place the engineering and other controls needed to establish respiratory isolation for patients with infectious diseases transmitted by airborne means (as discussed in chapter 6), it would be reasonable to require that program to make those services and its facility available to a patient with TB in the infectious stage. Or, if a methadone maintenance treatment program has the staff and resources to provide medication and counseling services to home- or hospital-bound clients whose illnesses make them temporarily unable to come into the program -- and it accommodates clients with other illnesses in this way -- it would be reasonable to require the program to offer the same accommodation to a patient who is temporarily home- or hospital-bound because of infectious TB. (Staff performing these duties would have to understand and employ the precautions necessary to prevent TB transmission.)

On the other hand, it would not be reasonable to require a program that did not have the resources to hire a physician who is an expert in TB to treat its infectious patients (or staff) or to provide a comprehensive array of primary care services for patients (or staff).[3] It would also not be reasonable to ask a program to transform itself, for example, from a nonresidential to a residential facility with the capacity to house and treat infectious patients. And, of course, it would not be reasonable to ask a program to allow its patients and staff to be exposed to active TB disease. Reasonableness depends on the resources and circumstances of the given facility.

Meeting the Federal Mandate To Prevent the Transmission of TB

Given the prevalence of TB in certain regions and populations, AOD programs may not be able to altogether eliminate the risk of TB for their patients and staff. However, programs can sharply reduce the probability of transmission by taking some or all of the following measures.

Cooperation With Public Health Officials

AOD programs should seek to cooperate and even collaborate with local or State public health officials in reporting cases of TB, developing policies for the prevention of the transmission of TB among their patients and staff, and providing followup for patients or staff who have or may have TB. Public health officials may be able to provide health care workers to screen, evaluate, and treat patients or staff who are or may be infected with TB, or who are suspected of having active TB. Public health officials can also arrange to conduct contact investigations, provide directly observed therapy, and provide followup for patients who have completed AOD but not TB treatment. Finally, public health departments should also be able to assist programs in conducting TB risk assessments and in educating program patients and staff about TB.

Programs Should Assess the Risk of TB to Their Patients and Staff

The rate of TB in the United States varies from region to region and group to group. For a facility to develop an effective TB infection-control program, it must have an accurate idea of the risk of TB in its community, its patients, and its facilities. As risk assessments should be done by an expert, programs should contact local public health officials for assistance in this matter. The resulting assessment -- which should be reviewed periodically -- should be the basis for the program's written TB infection-control protocol.

Programs Should Have a Written TB Infection-Control Policy

Programs should have written TB infection-control policies for both patients and staff. A TB infection-control policy should be based on a periodically reviewed risk assessment (see above). Programs should designate one or more persons to develop, enforce, and evaluate their TB infection control protocols. The infection control policy should include (1) a questionnaire that screens for TB disease, (2) screening for TB infection, and (3) referral for evaluation and treatment.

Networking To Stop TB and Improve Patient Services

The risk of TB transmission is lessened to the extent that a patient remains in recovery. Accordingly, AOD programs should try to be part of a health and social services network that can provide supportive services to their patients. That network should include:

- Public health officials
- Welfare or public assistance authorities
- Child and family services
- Family planning
- Mental health
- Maternal and child health services
- Domestic violence services
- Public housing authorities
- HIV/AIDS service organizations
- Criminal justice.

Pre-Admission Screening

AOD programs should endeavor to identify patients with infectious TB as soon as possible. The criteria used to detect infectious TB should be based on the prevalence of TB and other characteristics of the population served by the program. Programs should have a pre-admission protocol that includes a questionnaire that focuses on TB signs and symptoms, PPD results, past TB diagnoses, and TB treatment and therapy, if any. The pre-admission protocol should include PPD skin testing for high-risk applicants (see chapter 3). Applicants with TB symptoms should be referred immediately for a medical evaluation and admitted only after being cleared for non-infectiousness by a physician.

Patient Questionnaire

AOD providers can easily incorporate items regarding TB symptoms and history into existing admission/intake questionnaires. Such questionnaires must be formulated in language that will be easily understood by the patient. The questionnaire should pay special attention to the following symptoms: a cough that lasts for 3 weeks or more, persistent fever, night sweats, unexplained weight loss (more than 10 percent of body weight over a 90-day period), and the coughing up of blood. The questionnaire must also address the applicant's history of TB, if any, including the

date of diagnosis, the type of treatment received, the duration of the treatment, and the outcome of treatment. The questionnaire should also elicit information that will help the program determine whether the prospective patient is a member of a group that is at high risk for TB. Finally, the questionnaire should inquire as to whether the patient is on any TB medications that may need monitoring.

PPD Skin Tests

Depending on State law, programs should institute PPD skin testing for all high-risk patients. PPD skin testing serves to detect TB infection and the potential need for therapy to prevent certain high-risk persons from progressing to active TB disease. State, not Federal, law will determine who can perform TB testing, and whether -- as is generally the case -- an individual's consent is required for these and other medical tests. Programs unable to provide on-site testing may have to refer patients to a medical clinic or public health department for the test. Programs that propose to do the test on-site must ensure that the relevant staff are properly trained in PPD administration, reading PPD results, and patient counseling.

Persons with a prior positive tuberculin skin test should not be skin tested again unless the results of the earlier test and subsequent medical evaluation cannot be documented. Such persons should be referred for a one-time baseline chest x-ray and medical evaluation.

Since individuals generally have the right not to undergo medical testing or treatment without their prior informed consent, programs should obtain their patients' consent to TB testing before conducting such tests. Of course, some applicants may refuse to be tested. They may fear contracting TB from the test, that the results will be used in some adverse way by child welfare officials, immigration, the criminal justice system, or others. While they would be within their rights to refuse testing, applicants should be reassured that the test cannot transmit TB, that the results will not be reported except where required by public health law, and that the test is critical to the screening process. The importance of skin testing to the screening process must be stressed to the patient or applicant. (It may be helpful to share the policy requiring employee TB screening with patients to demonstrate the shared concern for TB.)

Finally, patients must be assured that they will be assisted in getting what TB services they may need, either at the program or through an appropriate referral. While a policy of making admission to treatment contingent upon an individual's consent to undergo TB testing would probably not be found to violate Federal disability discrimination laws (as discussed in appendix D), programs should check their own State law requirements before instituting such a policy.

Other Diagnostic Procedures

Additional diagnostic measures that are necessary for applicants or patients who may have infectious TB include a physical examination, a chest x-ray, and the microscopic examination and culture of sputum or other specimens. These are discussed in some detail in chapter 3.

Reporting Suspected or Confirmed Cases of TB

As previously discussed, programs conducting TB screening must report suspected or confirmed cases of TB to local or State public health departments. Chapter 4 discusses how AOD programs may accomplish this without breaching patient confidentiality.

Treatment of Those with TB

No TB services protocol would be complete without provisions for treatment or appropriate referral for treatment.

Training of Intake Personnel

Intake personnel must be able to identify the signs and symptoms of active TB. Applicants who are suspected of being infectious should be isolated and referred for treatment. Appropriate intake policies should be in writing. Public health officials should be consulted in drawing up practical and safe intake procedures.

Admission Policies

Programs may not use the results of either the questionnaire or PPD skin test as a basis for denying AOD services to an applicant who otherwise satisfies the program's eligibility requirements, unless he or she poses a significant health risk to others and the program cannot eliminate that risk through a reasonable accommodation. An applicant who poses such a risk should be considered for deferred admission, that is, his or her admission should be made contingent on treatment and a medical determination that he or she is free from infectious TB and poses no significant risk of transmitting TB to others. (It should be noted that drug-sensitive strains of TB can be rendered noninfectious in very little time.) Where an infectious applicant does not have a private physician, or where the program does not provide medical services directly, the program should make an appropriate referral.

Infected Applicants

There is no reason to deny AOD treatment to TB-infected applicants who are not infectious. In fact, it would be illegal to discriminate against them on the basis of their illness. Such persons may safely participate in AOD treatment whether or not they are on medication. If they are on medication, of course they will need to be monitored, since failure to adhere to treatment can lead to their becoming infectious or developing drug resistance.

Applicants With a History of TB

If a substance abuser has a history of TB, the provider or the evaluating physician must ascertain whether he or she completed previous TB therapy. Ultimately, only a proper medical evaluation can determine whether the applicant is currently infectious and whether it would be best to defer admission until further TB treatment is provided.

Recommendations for Typical Scenarios

Applicants for AOD treatment present with a variety of symptoms and histories. Risk assessments must therefore be made on a case-by-case basis. The following scenarios may be representative:

- **Positive PPD, no symptoms, recent negative chest x-ray**. Recommendation: Evaluate for preventive therapy. Begin AOD treatment.
- **No history of TB, 2 months of fever, 15 percent weight loss**. Recommendation: Perform PPD. If positive, report to health department (if required by State law, and without violating Federal confidentiality law). Arrange for complete medical assessment to rule out infectiousness. It would likely be legally defensible for a program to decide either to proceed with admission or to defer admission until the individual's potential infectiousness has been ruled out.
- **TB 6 months ago, on medication, no symptoms**. Recommendation: Consult public health officials, since patient may still be under case management by them. Consider bacteriologic examination of sputum. Monitor for adherence to TB treatment. Proceed with AOD therapy.
- **TB 6 months ago, did not complete course of treatment**. Recommendation: Consult public health officials. Provide full medical evaluation for infectiousness. Provide for followup. Do not admit without a medical determination of non-infectiousness.

Patients in Treatment for TB

All patients in treatment or preventive therapy for TB should be monitored on a monthly basis (as recommended by the CDC or State departments of health) for infectiousness (if the patient is receiving treatment for active disease), adherence to the therapy or treatment regimen, and side effects.

Followup Procedures

Patients should receive periodic followup or evaluation while in treatment. AOD providers and public health entities should collaborate on screening, evaluation, and necessary followup, including annual PPD skin tests (recorded in millimeters of induration for patients with prior negative PPDs, unless they are anergic). Where appropriate, this followup should include one-time chest x-rays (e.g., for a person with a newly positive PPD result) or sputum smears (where a patient has symptoms that could be due to TB). Screening at more frequent intervals is recommended where there is a high risk of exposure to TB.

Monitoring TB Treatment

Patients with TB disease who do not take their TB medication pose a significant threat to other patients and program staff. Nonadherence to the recommended course of treatment can lead to a recurrence of infectiousness or the development of MDR TB. Program staff should be involved in monitoring patients in TB treatment (or on preventive therapy).

In cases of suspected or confirmed nonadherence, a program should coordinate with local public health and medical providers to determine why the patient is nonadherent and to make sure that the patient resumes his or her treatment. Among other things, the program and local health officials might arrange to have a public health worker come to the facility and distribute the necessary medication on-site or arrange for the program to provide directly observed therapy. A program that disregards nonadherence is neglecting its responsibilities to the patient and others at the facility.

Substance Abuse Relapse

Substance abuse relapse can trigger a breakdown in other areas of the substance abuser's life. Where an AOD patient on TB medication relapses, special care should be taken to apprise the primary health care provider to make sure that the patient completes his or her TB treatment. A patient on TB treatment who relapses and experiences a prolonged interruption in TB treatment should be referred for medical evaluation.

Discharge of Patients

A patient who is receiving preventive therapy or treatment for TB should not be discharged without a plan for continued therapy or treatment. The program should coordinate with the primary care provider and public health department to ensure that the patient's therapy or treatment is not interrupted by the patient's discharge from AOD treatment. Ideally, the program will make certain that a followup appointment has been made with the primary care provider or public health department and that the patient has sufficient medication to cover the period between discharge and the appointment.

Screening of Employees

All employees should be counseled about TB and the risks of TB infection in the facility and in particular areas of the facility (see chapter 6). Special attention should be given to the dangers of infection for persons who are immunosuppressed. Employees should be screened for TB at the start of their employment and annually thereafter. This is an important element in TB-infection control. (Screening at more frequent intervals is recommended where there is a high risk of exposure to TB.) Between screenings, employees who are symptomatic must be immediately evaluated for active disease. Employees who have or are believed to have active disease must be excluded from the facility until active disease has been ruled out or the employee is determined to be noninfectious.

Training and Education

The education of staff and patients is crucial to stemming the TB crisis. This section will outline the range of training necessary to successfully implement a useful TB services protocol.

Trainers

A program should seek the assistance of State or local public health departments in establishing a TB training program. Collaboration on the training of staff and patients can strengthen the relationship between the program and those government entities responsible for tracking and treating TB and other communicable diseases. In exchange, the program might offer to train the latter in substance abuse issues.

Education of Staff

All staff should be trained in the basics of TB, including prevention, transmission, diagnosis, treatment, and followup. Any such training should address staff concerns about infection and disease. Staff should be advised that the safest way to proceed in dealing with TB in the AOD setting is to observe the TB services protocol. All staff should know the signs and symptoms of TB and must immediately refer employees or patients in need of medical evaluation to the program's TB services coordinator.

Counselors will need to be trained to field patients' questions about TB. Counselors should therefore be familiar with PPD skin testing, the importance of chest x-rays for individuals who react positively to PPD tests or have HIV infection, the basic symptoms associated with TB, the dangers of nonadherence, and other pertinent issues. All staff should be reminded of the importance of annual testing for employees.

Counselors should also be familiar with the health and social services network so as to be able to refer patients appropriately for both TB and other services. Counselors should be familiar with the key contacts at each of the agencies or organizations in the network. Counselors should be advised that part of their job in dealing with the agencies and organizations in the health and social services network is to advocate for program patients. Optimally, a program should have an employee trained to administer and read PPD skin tests or even provide directly observed therapy.

Education of Patients

Patient education and training should include the same basic information about TB, HIV, and other communicable diseases as is given to staff. Rather than relying exclusively on staff to convey this information, programs might employ methods such as peer education, group education, and joint staff and patient training. In this regard, it should be noted that peer counseling is a particularly effective means of bridging barriers to cooperation. Accordingly, a program might wish to give certain patients special training and responsibilities with respect to the training of other patients in the basics of TB.

Record Keeping for TB Services

The following information should be recorded for all patients and employees:

- Dates and results of PPD skin testing (including size of induration in millimeters)
- Date and results of chest x-ray
- Name of clinician
- Date and place of TB diagnosis
- Treatment recommended (including preventive therapy)
- Medical clearance for non-infectiousness
- Date treatment (including preventive therapy) was completed
- Date and place of referral for followup evaluation
- Results of followup evaluation.

The referral process should be documented by a form that will permit the program to document the nature of a referral, the results, and the progress of a patient's or employee's treatment or followup. If directly observed therapy or directly observed preventive therapy was given, the dates of each dose given should also be recorded. The local or State public health department can help design an appropriate record keeping system.

Evaluation of Test Conversions and Transmission of TB Within the Facility

Programs must be sure to evaluate patients or employees who convert from PPD-negative to PPD-positive, since test conversions may indicate that TB is being transmitted within the facility. (A conversion is a change of between 10 and 15 millimeters -- depending on the individual's age -- in the size of an induration resulting from a PPD skin test.) Where such transmission occurs, the program should call on public health officials to help the program review its risk assessment, determine the cause of the transmission, and prevent further transmission.

Endnotes

[1.] Specific questions and answers regarding TB-related discrimination in the AOD setting are set forth in appendix B.

[2.] The main nondiscrimination provision of the Rehabilitation Act is Section 504 (29 U.S.C. § 274). The Americans With Disabilities Act is cited as 42 U.S.C. § 12101 *et seq.*

[3.] 28 C.F.R. § 36.302(b).

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Chapter 6 -- Toward a Safe Workplace

Substance abuse programs must have and implement a TB infection control policy for the early detection, isolation, and treatment of patients or employees with active TB. An effective TB infection control policy will need to be in writing, will identify the person or persons responsible for supervising the implementation of the necessary controls, and will explain and emphasize the hierarchy of controls. The hierarchy of controls will include administrative controls, engineering controls, and, where necessary, masks (or personal respiratory protection). For smaller programs or programs with limited resources, the implementation of an effective TB infection control policy will depend on the program's ability to draw on the expertise and resources of local public health and occupational safety authorities. In devising a TB infection control policy, AOD employers must remember that a safe workplace is not only an ethical and legal obligation that benefits all concerned, it is the predicate for effective AOD treatment.

How Do We Determine the Risk of TB in a Particular Facility?

The measures a program will take to prevent the transmission of TB will depend on the incidence of TB among first, the surrounding population; second, its patients; and, third, its employees. The higher the incidence, the greater the risk of TB in the program. As the risk of TB increases, so will the intensity of the TB controls employed by the program. In conducting a risk survey, programs should draw on the expertise of local or State public health and occupational safety authorities. Such surveys should be reviewed both periodically and whenever employers have reason to believe that the risk of TB transmission in the facility may be different from what they previously believed, for example, after a nosocomial outbreak.

What Should a Program's TB Guidelines Say?

A program's TB infection control guidelines should be in writing, should identify the person or persons responsible for implementing it, and should explain and emphasize the hierarchy of controls.

Who Should Oversee a Program's TB Control Guidelines?

Only properly qualified individuals -- those who are trained about and understand what TB controls are appropriate and needed in their facility -- should be designated to oversee TB controls. A program without such an individual on staff should explore the possibility of

obtaining appropriate training through local public health or occupational safety agencies.

What Is the Hierarchy of Controls?

Both public health and occupational safety authorities recommend a hierarchy of controls in seeking to prevent the transmission of TB in AOD programs, with administrative controls being more important than engineering controls, and engineering controls being more important than masks. This hierarchy of controls is both cost-effective -- since administrative controls can cost very little -- and critical for minimizing the exposure of employees to undiagnosed TB.

Administrative Controls

Administrative controls are the key for minimizing the occupational acquisition of TB in an AOD program. Administrative controls are intended to result in the early detection of active TB among both patients and employees. Administrative controls will include screening mechanisms, such as patient and new employee questionnaires designed to elicit complete medical histories and to identify risk factors. (See chapter 5 for a discussion of questionnaires.) Administrative controls will also include tuberculin skin testing for new employees and written policies for the referral for evaluation and treatment of those who have positive PPD results.

Administrative controls will emphasize the importance to both patients and staff of identifying, isolating, and treating active disease at the earliest possible instance. Administrative controls will provide for periodic PPD testing and assessment of symptoms or chest x-rays for both patients and staff. In devising administrative controls, programs must proceed from this clear conviction with respect to TB: The best thing any program can do for its patients and staff is to put in place a policy that will result in the prompt identification, isolation, evaluation, and treatment of persons who pose a threat of transmitting the disease to others.

Engineering Controls

Because of the costs involved, and the expertise required to install and maintain them, the full gamut of engineering controls may not be possible or realistic for many AOD programs. Engineering controls involve developing specifically designated areas that meet the engineering standards for respiratory isolation. Such engineering standards are rigidly defined and are not commonly found, even in most hospitals. They include the use of adequate ventilation systems, high-efficiency particulate air filters, and special ultraviolet lighting in high-risk areas. Those controls are intended to reduce the concentration of infectious droplet nuclei in the air, prevent the transmission of such nuclei throughout the facility, or render the nuclei noninfectious by killing the tubercle bacilli they contain.

Assuming the space and resources, AOD programs in areas where TB and substance abuse are linked should try to develop an area or room with such controls. Such a project should be undertaken only in consultation with environmental engineers from the local or State public health departments or from other appropriate agencies or organizations. Once the appropriate engineering controls are in place, the designated area or room can be used as an isolation or holding area for any patient or applicant who is suspected of having infectious TB. The patient or

applicant will remain in this area until he or she can be transferred to a medical facility.

When Are Masks (or Respirators) Necessary?

Assuming that effective administrative controls are in place, masks are the least important of the three components of the recommended hierarchy of controls. This is at least true for the typical AOD program, since, generally, masks protect only the wearer. Masks are required only when interacting with someone who is or may be infectious, for example, when one is in the same room with such a person or when one is transporting such a person in an enclosed vehicle. Employees who may need to resort to masks to protect themselves must be instructed in their proper use. Masks should also be available for persons who are potentially infectious. Such persons should be isolated and instructed to wear masks and observe other precautions both while awaiting and during transfer to a medical facility. Unless a program functions as a full-service health care facility, employees should not attempt to counsel potentially infectious persons until infectiousness has been ruled out. Programs should contact local occupational safety experts for guidance as to the selection, use, and maintenance of masks, and the development of a respiratory protection program.

What Can a Program Do To Promote Workplace Safety?

No program which hopes to be effective can evade its legal and ethical obligations to provide a safe workplace. At the same time, it would be unrealistic to expect a field that routinely operates on shoestring budgets to be able to discharge those obligations without outside help. Outside help -- though constrained by the harsh budgetary realities of the mid-1990s -- can be secured through collaboration with local or State public health departments. With or without outside help, all programs should strive to develop TB workplace safety protocols that include the following features.

New Employees Should Be Screened for TB

New employees should be screened via an appropriately detailed questionnaire and a two-step PPD procedure (see chapter 5). Those with positive PPDs should be evaluated for symptoms and sent for chest x-rays to rule out infectious TB. If a new employee presents with suspected or confirmed infectious TB, he or she should be referred for appropriate evaluation and medical treatment; this employee should not be permitted to begin or return to work until infectious disease is ruled out. Employees should be counseled about the importance of participating in TB screening. Programs should bear the costs of screening procedures or arrange to have screening done by a public health agency.[1]

Employees Should Be Counseled About the Risk of Acquiring TB on the Job

Employees should be counseled regarding the specific situations that might put them at increased risk for TB. Counseling should occur at the earliest possible point in the hiring process and periodically thereafter. Special attention should be paid to the risks of acquiring TB on the job for those who are immunosuppressed, namely, those with HIV or other immunosuppressing conditions or those on immunosuppressive therapies. Employees (new or continuing) who are at

increased risk for TB should be given the option of working in areas where the risk of acquiring TB on the job is minimized. Working in a high-risk situation should be voluntary on the part of the employee. Unless it would cause undue hardship for them, employers must find alternative work for employees if they request transfer to a lower risk work situation. AOD programs must be particularly sensitive to those sorts of accommodations.

Employees Should Receive Annual PPDs

Employees should be given PPDs annually. Careful records should be kept to identify

on-the-job converters. Employee records should also reflect whether a given employee does or does not have contact with other employees. Such records can help programs to identify inadequacies in their controls. Finally, as with initial screenings, the employee should not have to bear the costs of an annual PPD.

PPD Conversions Must be Analyzed

Programs must analyze PPD conversions to determine whether conversions are a result of patient contact. If so, this is evidence that a program's administrative and other controls are inadequate, and that the program is seeing patients with unrecognized TB. A program that encounters such problems should review its risk assessment.

Contact Investigation Policy

Programs should have a contact investigation policy to determine the source of on-the-job exposures to TB. An appropriate policy will provide for:

1. The identification of those exposed to TB on the job
2. PPD testing at baseline and after 12 weeks to identify those who convert as a result of the exposure
3. Evaluation for active disease
4. Referral for treatment or preventive therapy (or provision of same).

Employee Training on Workplace Safety

Employees should receive annual training on TB and workplace safety. Attendance at such training should be mandatory and should be recorded. The training must be conducted by someone who is versed in both TB and the workplace safety features outlined above. This training should be supplemented by a TB library for both patients and staff. Programs should not rely on videotaped training unless the tapes are presented by someone who can answer employee questions about TB and workplace safety.

Review of Workplace Safety Practices

Programs should periodically review not only their risk assessments and on-the-job conversion

rates, but also their employee infection control practices.

Programs Must Be Careful Not To Discriminate Against the Disabled

Federal law protects current and prospective employees from discrimination based on disability. Under these laws, AOD programs may not deny or terminate employment on the basis of a person's TB status, unless there is a high probability of substantial harm to others and that probability cannot be reduced or eliminated by some reasonable accommodation. An employer must be willing to make a reasonable accommodation unless to do so would cause an undue hardship. Since a person with infectious TB can be rendered noninfectious in a relatively short time, it is unlikely that any but the smallest program would experience an undue hardship by agreeing to make a reasonable accommodation for an employee, new or old, who has infectious TB.

A reasonable accommodation might mean delaying the start of employment for several weeks or even a couple of months, or giving an employee an extended leave of absence. At any rate, a blanket refusal to hire someone who is infectious but willing to undergo appropriate treatment, or a policy of firing infectious employees who are willing to undergo treatment, would not only be illegal, it would fly in the face of what AOD programs stand for: a chance to recover.

Programs Must Observe Confidentiality as to Employee Health and TB-Related Information

A properly designed TB workplace safety protocol will generate a variety of records, from questionnaires containing detailed medical histories to logs that document PPD results and occupational exposures to TB. The confidentiality of those records must be observed.

Endnotes

[1.] In dealing with applicants, employers should note that it is illegal to ask about current or past medical conditions, including TB, until after a job offer has been made. Similarly, an employer may not require an applicant to take a physical or other sort of medical examination until after the extension of an offer of employment. Nevertheless, an employer may make the job contingent on a job-related medical examination, and the applicant may be so informed. The purpose of the prohibition on pre-employment medical examinations and inquiries into applicants' medical conditions or histories is to ensure that employers make hiring decisions on the basis of an applicant's current ability to perform job-related functions -- not on the basis of a current, past, or perceived disability.

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Appendix B -- Legal Questions and Answers Regarding TB-Related Discrimination in the AOD Setting

These questions and answers are based on an analysis of the two Federal laws prohibiting disability-based discrimination: the Rehabilitation Act of 1973 and the Americans With Disabilities Act (ADA).

1. Pre-admission Inquiries

Q: Is it legal for an alcohol and other drug (AOD) treatment program to ask an applicant for AOD services whether he or she:

1. Is currently infected with TB?
2. Has infectious TB disease?
3. Has a history of TB infection or infectious disease?
4. Is currently being treated for TB infection (prophylaxis) or infectious TB by a health care provider?

A: Yes, if obtaining such information is needed to enable the program to provide services or to ensure its safe operation.

As a general rule, a program subject to the Rehabilitation Act and/or the ADA may not ask a prospective client whether he or she has a particular disability simply for the purpose of identifying and excluding all people with that disability from obtaining admission into the program.

However, a program is permitted under both statutes to ask questions designed to determine whether the individual is qualified to receive its services -- that is, able to meet the program's essential eligibility requirements.

Since many AOD programs are required as a condition of receiving Federal Substance Abuse Prevention and Treatment block grant funds to make TB counseling, testing, and treatment available to their clients, they have solid justification for incorporating TB status inquiries into their admission policies. Therefore, an AOD program may ask a prospective client about his or her TB status and history in order to determine: (1) whether the client has (or may have) a condition that would pose a significant risk to the health or safety of the program's other clients or staff -- as would infectious TB; or (2) whether the client will need TB services (or a referral for TB services) from the AOD program, along with its AOD treatment services.

Finally, some AOD programs may have legal obligations under their own State's laws to examine all new program enrollees or applicants for communicable disease.

2.Admission and TB Testing

Q: Is it legal for an AOD treatment program to condition admission upon an applicant's consent to be tested for TB?

A: Yes. The Federal disability discrimination laws do not prohibit service providers, including AOD programs, from requiring applicants to undergo medical examinations, including TB tests, as a condition of receiving their services. But imposing such a requirement as a condition of admission must be justified either because it addresses the legitimate safety concerns of the program or because it is consistent with the need to provide the services the program offers.[1]

As is discussed in the previous question, TB testing of applicants for AOD services can be justified for both of these reasons. And again, if a program is subject to the Federal TB services mandate, it may justify the testing requirement as a means by which the program can fulfill its obligations to make TB counseling, testing, and treatment available to its clients.

While an AOD program may require a client to submit to a TB test (or supply that information in response to pre-admission inquiries), the program may not act in a discriminatory manner with respect to the test results. The relationship between a client's TB test results and an AOD program's admission practices will be discussed in the next series of questions.

3. TB Test Result and AOD Program Admission Practices

Q:Is it legal for an AOD program to refuse to admit an applicant for AOD services who is --

1. Known to have TB infection?
2. Known to have infectious TB disease?
3. Suspected of having TB infection/infectious disease?
4. Known to have a history of infectious TB disease?
5. Known to have MDR TB or a history of active MDR TB?
6. Suspected of having MDR TB?

A:The answer in each of these cases varies, and depends on the answers to two other key questions.

The first question that must be addressed is: Would admitting this individual create a direct threat to others -- that is, pose a significant risk to the health or safety of other clients or staff. As was noted previously, the determination of whether and when an individual with any disability poses a "significant risk" to the health or safety of others must be made on an individualized

basis. That individualized assessment also must be based on medically sound knowledge and facts -- not speculative assumptions or unfounded fears -- and must take into account:

- The actual nature of the risk (i.e., in the context of TB, how the disease is transmitted, and whether a particular individual has active, infectious TB and is therefore capable of transmitting it to others)
- The duration of the risk (i.e., the length of contagiousness)
- The severity of the risk (i.e., the potential for harm to others if TB infection is actually transmitted)
- The probability that the potential injury will actually occur (i.e., how likely is it that transmission will occur?).

If the answer to the first question with respect to any of the TB-related conditions listed above is "no," the condition does not pose a significant risk and that ends the inquiry. It would be illegal to refuse admission to the individual in question.

But if the answer is "yes," the individual does pose a significant risk to others, the program must ask and answer a second question: Are there reasonable modifications the program can make to its practices, policies, or rules that will eliminate or mitigate the risk. If there are, those modifications must be made. If there are not, the program may lawfully exclude the individual from receiving services for as long as the significant risk to others (or inability to accommodate) continues to exist.

How these questions are answered with respect to specific TB-related conditions is discussed next.

TB infection only. Because TB infection absent clinical disease is not contagious to others, admitting and serving a client infected with TB would pose no risk to other clients or staff. Therefore, it would be illegal to exclude individuals from AOD treatment solely because they are known to have TB infection.

Current active TB disease. Whether an applicant with active TB poses a significant risk to others depends on whether his or her disease is (or may be) currently infectious. Only people with pulmonary or laryngeal TB have the potential to transmit tubercle bacilli to others. Moreover, the period of infectiousness will depend upon whether the patient is taking tuberculosis medication that is successfully keeping him or her noninfectious.

A person with active and infectious TB does pose a real risk of transmission to others in institutional settings like AOD programs, where other clients and staff share common air space with the infectious individual for repeated or extensive periods of time. This risk is more serious when the program is a residential one, and contact is prolonged, but it exists in outpatient settings as well. And, while it is generally treatable and curable, TB is nonetheless a serious disease with potentially fatal consequences if not treated appropriately.

Active infectious TB disease, therefore, can legitimately be seen as posing an actual and significant risk to others. As a result, putting in place policies and procedures designed to

identify those who have infectious TB disease is perfectly justifiable. And denying admission to those individuals who are diagnosed with or show symptoms of infectious TB disease may also be justified -- if it is not possible to eliminate the risk of transmission by making reasonable modifications to the program's policies, rules, or procedures.

What about MDR TB. Is it legal for an AOD program to refuse to admit an applicant known to have active TB disease that is multidrug resistant. Again, the answer depends upon whether the applicant is infectious and whether the program is able to accommodate that risk. The fact that the TB disease is multidrug resistant is relevant to the determination of infectiousness. People with MDR TB may be infectious for a longer period of time than people with drug sensitive TB disease because of the difficulty in finding which combination of drugs are effective in attacking the tubercle bacilli.

A history of TB infection and/or active TB disease. A history of TB infection and/or a record of prior episodes of active TB are disabilities for purposes of the ADA and the Rehabilitation Act. It would be illegal for an AOD program to deny admission automatically to persons with such medical histories solely because they have such histories and without regard to whether they pose any present actual risk to other clients or staff. A history of TB infection or disease does not, by itself, provide any evidence of current disease or infectiousness.

If, however, a program concludes on the basis of reasonable medical judgment that the person has active TB and is currently infectious, then the program may deny admission for the period of infectiousness (assuming that no reasonable accommodations can be made.)

Suspected (but not confirmed) TB infection or disease. It is illegal under the Federal antidiscrimination laws to deny admission to an applicant for AOD services solely because of the suspicion that he or she may be infected with or have a contagious disease, including TB. An AOD program may, however, confirm the suspected diagnosis before deciding whether to admit such an individual. It may condition admission on the applicant's undergoing (or disclosing the results of) a medical examination to ascertain the diagnosis and fact or lack of infectiousness, or it may suspend or delay its admission decision until it obtains the medical information it needs to assess whether the applicant has a condition that poses a risk to other clients or staff.

4.Continuation of AOD Treatment and TB Treatment

Q No. 1: Is it legal for AOD programs to have policies that require as a condition of receiving and/or continuing in AOD treatment that an applicant or client with TB infection undergo TB prophylaxis?

A No. 1: No. Individuals generally have the right to make medical treatment decisions for themselves, and may not be subject to medical treatment without their voluntary informed consent after being apprised of the risks, benefits, and possible side effects of the proposed treatment. Although offering TB prophylaxis to individuals with TB infection may well prevent or reduce their risk of developing active disease in the future -- and is highly

recommended by public health authorities for this reason -- the decision whether to undergo preventive therapy remains the choice of each individual.

Since latent TB infection is not contagious and does not pose a risk of transmission to others, and since being infected with TB does not inevitably result in active infectious disease in every case, it would be difficult for an AOD program to justify a requirement that all TB-infected clients undergo TB prophylaxis on the grounds that such a requirement is necessary to ensure the safe operation of the program, or to protect other clients or staff from a significant risk to their health.

A policy of requiring infected (but not infectious) clients to undergo TB prophylaxis as a condition of receiving alcohol or other drug treatment could therefore make an AOD program vulnerable to a charge of discrimination against individuals with the disability of TB infection in violation of the Rehabilitation Act and the ADA.

Q No. 2: Is it legal for AOD programs to have policies that require as a condition of admission or continuation in AOD treatment that individuals with active TB disease undergo treatment for their TB?

A No. 2: For most programs, using the analysis set out before, the answer is likely to be "yes." Because individuals with active, untreated TB disease are -- or are likely to become -- infectious to others, a program could justifiably decide that such patients pose a significant risk to themselves and others. If no reasonable accommodations can be made to eliminate that risk -- and, indeed, conditioning such patients' participation in AOD treatment on their agreeing to be treated for TB is perhaps the best way to address that risk -- then a policy of requiring clients with active TB to undergo TB treatment in order to receive or remain in treatment would not violate the Federal antidiscrimination laws.

However, an AOD program cannot force a client to take TB medication if the client does not consent because, again, individuals generally have the right to make medical care decisions for themselves. Should a client with active TB refuse to undergo TB treatment, the AOD program would be faced with a very real dilemma. It could enforce its (legally defensible) policy by denying the client further substance abuse treatment services; or it could allow an individual who poses a very real risk to both his own and others' health to continue receiving the AOD services he or she also needs -- services that may in fact offer the best hope there is to enable him or her to get the TB care he or she needs as well. One possible solution to this dilemma might be to arrange for the patient's voluntary transfer to another AOD program that is willing and able to deal with his or her need for both AOD and TB care.

(A State's TB control law may authorize the compulsory commitment of individuals with TB who pose a threat to the health or safety of others, and may permit such individuals to be detained unless and until they undergo treatment. But the authority to do this is generally left in the hands of the public health authorities and/or the courts -- not individual health care providers. An AOD provider that decides to refuse admission to or to discharge a client who refuses to

undergo or comply with needed TB therapy has the option of notifying the public health authorities of this fact, but it must do so in a way that complies with the Federal AOD confidentiality law and regulations. See chapter 4 for a discussion of this issue.)

Q No. 3: Is it legal for AOD programs to have policies that require as a condition of receiving and/or continuing in AOD treatment that an applicant or client with a prior history of TB disease (who completed TB treatment) undergo TB prophylaxis?

A No. 3: No. For the same reasons a policy requiring TB-infected clients to undergo prophylaxis would be subject to legal challenge, a policy requiring those with a history of TB that has been successfully resolved to undergo preventive therapy could also be challenged on the grounds that (1) it interferes with the right of individuals to make medical treatment decisions for themselves, and (2) it discriminates against individuals on the basis of a disability (a record of TB) that does not prevent them from satisfying the essential eligibility criteria for participation in AOD treatment and does not pose a significant risk to others in the program.

Q No. 4:Is it legal for AOD programs to have policies that require as a condition of receiving and/or continuing in AOD treatment that an applicant or client with a history of TB disease (and incomplete TB treatment) undergo TB treatment?

A No. 4:Yes, at least for those with active disease. If the program suspects that due to incomplete treatment the client may still have active disease, the program may require the person to be tested to determine whether active disease is present and, if so, may give the client the choices outlined in answers to Question No. 2. If the client is not currently diagnosed as having active TB, the program may not have a policy requiring such individuals to undergo TB treatment.

5. TB Monitoring Requirements

Q:If a client is participating successfully in AOD treatment and is known to have latent TB infection of a history of prior active disease, is it legal for the AOD program to require, as a condition of remaining in the program, that the client undergo periodic examinations to determine if he or she has progressed to active TB?

A:Yes, assuming that such diagnostic medical examinations are justifiable because they can be shown to be necessary for the provision of AOD services and/or the safe operation of the AOD program, such a policy would not violate the antidiscrimination provisions of the Rehabilitation Act or the ADA. A

medical monitoring program designed to identify those TB-infected patients who are currently at high risk of and/or showing symptoms of (re)developing active, infectious TB could well be justifiable under the standards discussed in Question No. 2.

6. Monitoring Completion of TB Therapy

The Federal laws prohibiting disability-based discrimination are not directly relevant to this topic. Instead the following questions implicate other laws and ethical and policy concerns that AOD programs may wish to address even in the absence of legal rules that resolve noncompliance issues.

Q: Does an AOD program have any obligation to monitor a patient's compliance with TB treatment rendered outside the AOD program?

A: No Federal law specifically addresses this question. However, as noted in chapter 4, IV.B, the Federal Centers for Disease Control and Prevention (CDC) guidelines and Occupational Safety and Health Administration (OSHA) enforcement rules for preventing and controlling the transmission of TB in health care settings -- including at least certain substance abuse treatment programs -- stress the importance of implementing TB control policies that, among other things, will enable such providers to identify and monitor the treatment of clients and staff with or at risk for active TB disease. While it is not altogether clear that these Federal guidelines and enforcement rules create an absolute or enforceable legal duty on the part of AOD programs to monitor their clients' TB status and treatment -- wherever that TB care may be provided -- doing so would certainly be prudent from a practical as well as a legal point of view.

In light of this, it would clearly be permissible for an AOD program to require a client receiving TB treatment elsewhere to tell (or allow) his or her TB treatment provider to communicate with the AOD program regarding the client's compliance with TB treatment.

7. Reporting Noncompletion of TB Therapy

Q: Do AOD programs have a legal obligation to report a client's noncompliance with TB treatment provided by the AOD program itself?

A: The answer depends on State law, which varies. Some State (and local) public health/TB control laws impose on health care providers who diagnose and treat an individual for TB a continuing obligation to report the patient's progress in treatment -- and compliance with or failure to comply with the prescribed treatment -- to the local and/or State public health/TB control authorities. AOD programs serving as their clients' TB treatment providers in

these States will have a legal duty to make these mandated reports. (Chapter 4 discusses the various ways that AOD providers who have such reporting obligations can fulfill their State-law duties without violating the Federal AOD confidentiality law and regulations.)

8. Confidentiality

Q: If AOD programs are supposed to report all cases of active, infectious TB to public health officials, won't that violate our clients' right to confidentiality?

A: Not if you follow the guidelines outlined in chapter 4. You can and should report active, infectious TB cases to public health officials by obtaining patient consent or by drawing up a qualified service organization agreement (QSOA) that limits where that information is going and for what purpose. (A sample QSOA may be found in appendix C.)

9. Liability

Q:Are AOD providers obligated to inform potential clients that there may be individuals who are TB-infected or undergoing treatment for active TB on the premises?

A:Not in such ominous terms. AOD providers can explain that in accordance with the Federal Block Grant Mandate, they are required to provide TB services to all clients.

Endnotes

[1.] 42 U.S.C.A. § 12182(b)(2)(A)(i); 28 C.F.R. § 36.301.

The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
Treatment Improvement Protocol (TIP) Series 18

Appendix C -- Sample Forms

Sample Form No. 1: Consent for the Release of Confidential Alcohol or Drug Treatment Information

I, _____, authorize

(Name of patient)

_____
_____

(Name or general designation of program making disclosure)

to disclose to
_____ the
(Name of person or organization to which disclosure is to be made)

following information:
_____
(Nature of the information, as limited as possible)

_____
_____
_____
_____

The purpose of the disclosure authorized herein is to: _____
(Purpose of disclosure, as specific as possible)

_____
_____

I understand that my records are protected under the Federal regulations governing confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

(Specification of the date, event, or condition upon which this consent expires)

_____
_____

Dated: _____

_____

Signature of participant

_____

Signature of parent, guardian, or authorized representative when required

Page Down

Sample Form No. 2: Prohibition on Redisclosure of Information Concerning Client In Alcohol or Drug Abuse Treatment

This notice accompanies a disclosure of information concerning a client in alcohol/drug abuse treatment, made to you with the consent of such client. This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Sample Form No. 3: Consent for the Release of Confidential Alcohol or Drug Treatment and [TB] [STD] [HIV/AIDS] Information To Comply With Disease Reporting Requirements

I, _____ authorize

(Name of Patient)

The ABC Substance Abuse Program

_____ to

disclose to

(Name of general designation of program making disclosure)

the [State and/or local] Department of Health officials authorized to require and receive mandated [HIV/AIDS/STD/TB] reports

_____

_____

(Name of person or organization to which disclosure is to be made)

the following information: (Nature of the information as limited as possible)
(1) information that State law requires to be reported about my diagnosis and treatment for -- [initial any which apply]
_____ HIV infection
_____ AIDS
_____ STD (sexually transmitted disease)
_____ TB (tuberculosis)
(2) my name and other personal identifying information, if required to be reported by State law; and
(3) information about my status as a patient in alcohol or drug treatment, if required to be reported by State law.
The purpose of the disclosure authorized herein is to:
allow my alcohol or drug treatment program (named above) to comply with State law(s) requiring the reporting of cases of [HIV/AIDS/STD/TB].

_____

(Purpose of disclosure as specific as possible)

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that HIV-related information about me, STD-related information about me, and TB-related information about me is protected by State law and cannot be disclosed unless the disclosure is authorized by State law. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

_____

(Specification of the date, event, or condition upon which this consent expires)

_____

_____

_____

_____

Dated: _____

_____

Signature of Patient

Sample Form No. 4: Consent for the Release of Confidential Information About Alcohol or Drug treatment and [TB] [STD] [and/or] [HIV/AIDS] Care

I, [name and address of patient], authorize --

- the following alcohol or drug treatment program(s): [name and address of each treatment program authorized to make and receive disclosures], **AND**
- the following health care provider(s): [name and address of each [TB][STD] {and/or][HIV/AIDS] care provider authorized to make and receive disclosures], **AND**
- [designate staff of the State/local Department of Health responsible for [TB][STD] [and/or] [HIV/AIDS] prevention, control and care; specify appropriate name and address] --

to communicate with and disclose to one another the following information:
[initial each category that applies]*

*_____(1) **Alcohol or drug treatment**: Information about my participation and attendance in the alcohol or drug treatment program(s) named above that is needed to enable the persons and agencies listed above to provide, coordinate, and monitor my treatment for [TB] [STD] [and/or] [HIV/AIDS].

*_____(2) **Tuberculosis (TB)**: Information about my diagnosis and treatment for TB that is needed to enable the persons and agencies listed above to provide, coordinate, and monitor my treatment for [TB] [STD] [and/or] [HIV/AIDS].

*_____ (3) **Sexually transmitted disease(s) (STD)**: Information about my diagnosis and treatment for any STD that is needed in order to enable the persons named above to provide, coordinate and monitor my treatment for the [TB] [STD] [and/or] [HIV/AIDS].

*_____ (4) **HIV/AIDS**: Information about my HIV status (including HIV test results and information about my diagnosis and treatment for HIV-related conditions, including AIDS) that is needed to enable the persons and agencies listed above to provide, coordinate, and monitor my treatment for [TB] [STD] [and/or] [HIV/AIDS].

The purpose of these disclosures is to (1) enable the persons and agencies listed above to provide, coordinate, and monitor the treatment I receive for [TB] [STD] [and/or] [HIV/AIDS]; and (2) discuss with me any [sexual/needle sharing] partners or contacts and/or family members who might be infected [with [TB] [STD] [HIV] and need treatment.

I understand that my alcohol and drug treatment records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that HIV-related information about me, STD-related information about me, and TB-related information about me is protected by State law, and cannot be disclosed except as authorized by State law.

I understand that I may revoke this consent at any time except to the extent that action has already been taken in reliance on it, and that in any event this consent expires automatically as follows:
[Specify the date, event, or condition upon which this consent expires.
This could be one of the following:
(1) The date on which my treatment for [TB] [the STD] is completed.
(2) A specific date (such as 6 months or 1 year) after the consent form is signed.]

Dated:
Signature of patient

Sample Form No. 5: Qualified Service Organization Agreement on Coordination of [HIV/STD/TB] Care (AOD Treatment Program and [HIV/STD/TB] Health Care Provider)

[Name of health care facility providing [HIV/AIDS/STD/TB] care to Program patients] ("the [HIV/AIDS/STD/TB] Care Provider") and the [name of alcohol or drug treatment program] ("the Program") hereby enter into a qualified service organization agreement, whereby the [HIV/AIDS/STD/TB] Care Provider agrees to [provide, coordinate, and/or monitor] the treatment and/or related services for [HIV/AIDS/STD/TB] being provided to patients of the Program who are diagnosed, treated, and/or provided related services for [HIV/AIDS/STD/TB] by the [HIV/AIDS/STD/TB] Care Provider.

Furthermore, the [HIV/AIDS/STD/TB] Care Provider:
(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the Program about the patients in the Program, it is fully bound by the provisions of the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and
(2) undertakes to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal confidentiality regulations, 42 C.F.R. Part 2.

Executed this _____ day of _____, 199___.
President
[Name of [HIV/AIDS/STD/TB Care Provider]
[address]
AOD Program Director
[Name of Program]
[address]

Sample Form No. 6: Qualified Service Organization Agreement on Reporting of [HIV/AIDS/STD/TB] and Coordination of [HIV/AIDS/STD/TB] Care (AOD Treatment Program and Health Department [HIV/STD/TB] Staff)

_____
[Name of relevant Health Department [HIV/AIDS/STD/TB] unit and staff]
("the Health Department [HIV/AIDS/STD/TB] Unit") and the

_____
[name of alcohol or drug treatment program] ("the Program")
hereby enter into a qualified service organization agreement, whereby the Health Department [HIV/AIDS/STD/TB] Unit agrees to [provide, coordinate, and/or monitor] the treatment and/or

related services for [HIV/AIDS/STD/TB] being provided to patients of the Program who are diagnosed and reported as having [HIV/AIDS/STD/TB] and are provided [HIV/AIDS/STD/TB]-related services by the Health Department [HIV/AIDS/STD/TB] Unit.

Furthermore, the Health Department [HIV/AIDS/STD/TB] Unit:

(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the Program about the patients in the Program, it is fully bound by the provisions of the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and
(2) undertakes to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal confidentiality regulations, 42 C.F.R. Part 2.

Executed this _____ day of _____, 199___.
President
[Name of [HIV/AIDS/STD/TB Care Provider]
[address]
AOD Program Director
[Name of Program]
[address]

The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
Treatment Improvement Protocol (TIP) Series 18

Appendix D -- Massachusetts Policy for TB Control in Substance Abuse Treatment Centers

POLICY FOR TB CONTROL IN SUBSTANCE ABUSE TREATMENT CENTERS

Massachusetts Department of Public Health
Division of Tuberculosis Control
Bureau of Substance Abuse Services
June, 1993
Alfred DeMaria, M.D.
Assistant Commissioner, State Epidemiologist and State Medical Director
for Substance Abuse Services
Sue Etkind, R.N., M.S.
Director, Division of Tuberculosis Control
Dennis McCarty, Ph.D.
Director, Bureau of Substance Abuse Services

I. BACKGROUND

Tuberculosis in the United States

In 1991, 26,283 tuberculosis (TB) cases were reported in the United States - an 18 percent increase over the number reported in 1985. From 1985 through 1991, over 39,000 excess cases of tuberculosis (TB) occurred in this country, compared with the expected decline of 7 percent per year observed from 1981 through 1984. Increases in TB have occurred in blacks and Hispanics and in the 25-44 year-old age group. They have been noted in the geographic areas of the country with the largest numbers of cases of Acquired Immunodeficiency Syndrome (AIDS).

The TB/HIV Connection

Evidence for the association between HIV and TB comes from several sources which include: the matching of both the AIDS and TB Case Registries; HIV seroprevalence surveys in several cities, including Boston, and data on coinfection among injection drug users (IDU) in New York and New Jersey.

In a New York City cohort of 480 methadone patients, 15 percent of HIV seropositives with documented prior TB infection developed TB over a 2 year period compared to none of the TB-infected HIV seronegative patients. With additional years of follow-up, the proportion of HIV-positive IDUs developing TB is expected to rise considerably. Therefore persons with both TB and HIV infection are at extremely high risk of developing clinically active TB.

The TB/Substance Abuse Connection

Alcoholics and drug addicts are at increased risk for TB because of the environments where many live and because of their elevated risk for HIV infection. Crowded conditions in shelters and at meal programs, where 40-50 percent of the guests and participants abuse alcohol and other drugs, contribute to the transmission of respiratory infections, including TB. Similar exposure risks are found in jails and prisons (75-85 percent of inmates have histories of alcohol or other drug abuse) and addiction treatment programs. In addition, HIV infection is prevalent among individuals enrolled in residential, detoxification, and methadone treatment programs. Injection drug use is now the leading risk behavior for new cases of AIDS in Massachusetts and is the third most prevalent risk factor associated with tuberculosis in the state. An analysis of the 1991 TB morbidity indicates that at least 14 percent of all TB cases reported during that period had a history of drug use. Data from two surveys conducted at the Boston City Hospital TB Clinic during that period had a history of drug use. Data from two surveys conducted at the Boston City Hospital TB Clinic during 1990 confirm that injection drug use and HIV infection are closely associated with tuberculosis infection or disease.

II. TB SERVICES IN SUBSTANCE ABUSE PROGRAMS

The rationale for providing TB screening and preventive therapy in substance abuse treatment programs include:

- Approximately 90 percent of the new TB cases which occur each year arise from the reservoir of dormant TB infection among some 10 to 12 million individuals in the population. A major public health goal is to identify infected individuals at highest risk of developing clinical TB, e.g., who are at risk for or have HIV infection and prevent disease in these people.
- TB is one of the few contagious respiratory diseases that occur in patients with HIV and AIDS, and it is treatable, curable and preventable.
- Clients with a positive tuberculin skin test are at increased risk of active TB, even in the absence of HIV infection, and are at high risk of active TB when HIV is present.
- TB skin testing of persons with, or at risk for, HIV infection and also at risk for TB should be conducted in the setting where individuals at risk for both conditions are routinely seen, e.g., substance abuse treatment centers.
- Men and women in treatment have better control over their addictive behavior and, therefore, are more likely to follow TB control recommendations.
- An effective TB screening and preventive therapy program will significantly reduce the risk of TB disease among clients and reduce the risk of transmission of TB infection from clients to treatment program staff and other clients.
- If taken as prescribed, INH preventive therapy has been shown to reduce the risk of developing disease by up to 90 percent among persons without HIV infection. Based on the good response of HIV-infected persons with active TB (disease) to standard TB drug therapy, INH preventive therapy also should be effective in this population.
- Because many treatment programs require frequent (often daily) contact with clients for extended time periods (weeks/months), there is a unique opportunity for the

treatment program staff to promote adherence by providing supervised preventive drug therapy (daily or on a twice weekly basis) for the recommended course of treatment (6-12 months). Such supervision can be facilitated by the simultaneous administration of INH and methadone.

- A referral network of 30 TB clinics statewide currently provides free diagnosis and treatment services for tuberculosis. (See attached list)

Because of the environmental and behavioral risk factors for TB found among individuals who abuse alcohol and other drugs, it is critical that addiction treatment programs have aggressive programs for TB screening, referral for TB services, and support for TB medication protocols. Programs should be targeted to both clients and staff.

III. GOAL

To identify, prevent and treat tuberculosis disease and infection among individuals and staff in alcoholism and drug abuse treatment programs.

IV. OBJECTIVES

1. To provide counseling and educational information about TB to clients and staff
2. To provide TB screening to determine whether clients have been infected with the TB organism
3. To evaluate TB-infected clients for active TB disease
4. To provide adequate and appropriate treatment for those clients found to have either tuberculosis infection or disease
5. To provide referrals to the responsible health departments for clients who are on TB treatment who have been discharged from substance abuse care
6. To provide referrals and TB information to clients who are refused services due to a lack of program capacity

V. PRIORITIES

1. Treatment centers that admit and treat more than 300 clients per year.
2. Treatment programs that admit and treat between 100 and 300 clients per year.
3. All other Programs that treat IDUs.

VI. PROCEDURES

A. FOR SITES WITH SOME CAPACITY FOR PRIMARY MEDICAL CARE

Long Term Treatment Sites (Methadone Maintenance, Recovery Homes, Therapeutic Communities):

Step 1: Admission Procedure:

1. During the client orientation session the importance of testing for tuberculosis will be emphasized in a non-threatening manner. All staff must be educated, supportive and committed to the need for this testing. Confidentiality measures for all patient medical information should be discussed and maintained.
2. The orientation session should also include individual HIV risk reduction counseling (with follow-up counseling as needed) done by trained individuals, and on-site voluntary HIV testing or referral options for such testing.
3. Every client will have a brief history taken which will include questions about previous TB exposure, skin test results, past treatment for TB and current symptoms which may be suggestive of tuberculosis (cough, fever, night sweats, etc.) If the client has documentation of successful completion of past treatment for TB (at least 6 months of therapy) and has no symptoms, then no further follow-up is necessary. If the client has symptoms, then he should be referred to the TB clinic for evaluation as soon as possible.
4. All clients with no documentation of a past positive skin test should receive a skin test for tuberculosis. The intradermal Mantoux technique (with 5 tuberculin units PPD) is the only acceptable test. The test results should be recorded in millimeters of induration (swelling). The skin test should be preceded by an explanation of the reasons for the test and the need for follow-up and preventive therapy if the skin test is positive.
5. For most clients, a positive skin test is one that measures 10 mm induration. However, there are some individuals for whom 5 mm would be considered positive. These clients include: those persons who are known to be HIV infected; persons who are injecting drug users, and persons who have had close contact to someone with active tuberculosis. All individuals with a positive skin test will be counseled about the significance of the positive result and referred to the local TB Clinic to be evaluated for clinical TB and appropriate treatment. Persons currently having symptoms suggestive of TB will be referred for evaluation as soon as possible - regardless of the size of the skin test reaction,.
6. Persons with a negative (0 mm) skin test reaction who are HIV infected or at risk of HIV infection (such as injecting drug users) should be evaluated for anergy by performing anergy testing using at least two control antigens (mumps, candida or tetanus) (see appended anergy testing guidelines). If the client is not anergic (e.g. there is some response to the anergy tests), and has no symptoms, then no further TB follow-up is required. If anergic (e.g. no skin test reaction), the client should be referred to the TB clinic for further evaluation.
7. For clients who can provide documentation of a past previous positive Mantoux skin test and no history of successful completion of TB therapy, a referral to the TB clinic should be made in order to rule out the possibility of active disease, and to evaluate the client for preventive therapy.

NOTE: At methadone treatment sites, skin testing and follow-up for persons who test positive, who have symptoms of TB, or who are anergic, should occur prior to the initial methadone dose

if possible. This serves as an adherence tool as well as to assure that there are no clients entering treatment who have TB disease who could put other clients or staff at risk of tuberculosis.

Step 2: TB Clinic referrals:

Whenever possible, all clients who need follow-up for a positive skin test, symptoms or anergy, should be referred to a TB Clinic where expertise in chest x-ray interpretation and tuberculosis treatment and care is available. If this is not possible, at a minimum, chest x-rays should be read by someone familiar with the varying radiologic presentations of TB. Follow-up is possible at the treatment site rather than the clinic, if adequate medical/nursing patient supervision is available.

Communications need to be developed with local TB Clinic staff to ensure that: a) scheduling is accomplished smoothly and efficiently for the client (it may be helpful to provide clients with a scheduled TB clinic appointment at the time that their skin test is read at the addiction treatment program); b) the TB clinician is aware of the client's HIV status, if known (client's consent required); and c) referred clients are promptly followed if they fail to keep a scheduled appointment. If the client fails to keep the first clinic appointment, a second appointment should be scheduled. Failure to keep the second appointment should result in a concerted effort to encourage and facilitate compliance.

Step 3: TB Follow-up:

1. Clients who have been referred who are infected, but do not have current TB disease, will be strongly encouraged to receive Isoniazid (INH) preventive therapy at the substance abuse treatment site. This will include all persons with a positive skin test and persons who are anergic with an abnormal chest x-ray. Administration of INH will be directly observed and provided on site daily or twice a week. Isoniazid may be given at the time that the methadone is dispensed. Some programs may wish to use a client "contract" as an adherence tool for completion of therapy. The use of informed consent for INH prophylaxis is an option for those programs who may feel that this documentation is necessary. (sample appended)
2. All persons on preventive therapy must be monitored by trained personnel for signs and symptoms of adverse reactions during the entire course of treatment. Some patients will have underlying liver disease due to previous alcohol or other drug abuse. Although chronic liver disease is not a contraindication to INH preventive therapy, such patients should be monitored more carefully by symptom review and liver function testing (LFT) (see appended LFT guidelines). These reviews should be documented on the client's medical record. A symptom check off list may be useful for this purpose. (sample appended)
3. Clients who are lost to follow-up before completing at least 6 months of uninterrupted preventive TB therapy, but who are now re-enrolled should be referred to the TB clinic for evaluation for restarting therapy. When the client is scheduled to leave the treatment site before completing at least 6 months of preventive TB therapy, a well

coordinated transition will be arranged to ensure completion of preventive therapy at another health care facility, e.g., a TB Clinic.

4. Clients found to have TB disease will be placed on appropriate therapy by the local TB Clinic. Supervision of therapy and follow-up examinations will be the responsibility of the TB Clinic.

B. SUBSTANCE ABUSE PROGRAMS WITHOUT PRIMARY CARE CAPACITY:

Detox or other short term stay facilities

Step 1 should be followed, as above, as soon as the client is able to understand the needed education, counseling and medical history instructions.

Due to the nature of this type of service, however, there will not be adequate time for Steps 2 and 3 (referrals and follow-up) before the client is discharged from the facility.

Clients who are symptomatic for TB, however, must be referred as soon as possible to a TB clinic or other health care facility (if tuberculosis-specific clinics are unavailable), for evaluation for active disease (as their continued presence may jeopardize other clients and staff).

Client's skin test results should be recorded in the client's medical record in such a place that allows easy reference when and if, the client returns to that facility. This system will help to avoid retesting clients who have already tested positive in a previous encounter. The client should also be given a copy of his skin test result. For those clients who were skin test positive (or anergic), education should be provided as to the need for follow-up by a TB clinic after discharge, a list of TB clinic addresses and telephone numbers should be part of the discharge information provided, and if possible, an appointment made at a TB clinic for follow-up.

C. FOR OUT-PATIENT COUNSELING SETTINGS:

Educational information about the relationship between TB and HIV and the needs for skin testing of designated high risk groups should be made available to the clients attending these sites. A TB clinic directory and other language specific resource material should be accessible. Counselors should stress the importance of skin testing as part of their intake procedures.

D. FOR CLIENTS DENIED ADMISSION DUE TO A LACK OF CAPACITY OF THE PROGRAM:

All clients who are denied admission should be given information relative to available tuberculosis services (TB Clinic list) and the need for testing (sample brochure appended).

E. STAFF RECOMMENDATIONS:

All staff should be educated as to the TB/HIV problem, skin testing procedures and interpretation, and the need for follow-up and preventive therapy for their high risk clients.

Because some staff may have prolonged contact with clients who have undiagnosed TB disease, it is recommended that all new employees obtain a skin test upon employment. Those employees who are skin test positive (10 mm or more reaction), should be referred to the TB clinic for evaluation and possible preventive therapy. Those employees who are skin test negative, should be retested annually thereafter. Employees who subsequently "convert" their skin test to positive at the annual screening, should be referred to a TB clinic for evaluation.

F. ACTIVE TB AT A SUBSTANCE ABUSE SERVICE SITE:

If an active case of TB is detected among clients or staff of a substance abuse service site, the local Health Department, in conjunction with the Division of TB Control, will conduct a contact investigation on site. All persons with prolonged close contact to the case then will be required to be tested (if not previously positive) and followed up as necessary.

G.ENVIRONMENTAL CONTROLS

As noted, crowded conditions and poor building ventilation predisposes to TB transmission, especially in residential treatment centers when the duration of possible exposure is greater. Centers with clients at high risk for TB should consider environmental interventions to make TB transmission less likely. Ventilation should be checked for proper function on a regular basis at least twice yearly, for example, while changing to and from the heating cycle. Professional engineering advice should be sought, if necessary. Systems should be balanced if necessary for optimal performance. Upper room ultraviolet germicidal irradiation may be useful in some settings to reduce TB risk. The TB Division can offer technical assistance on the use of UVGI and other air disinfection strategies.

VII. RESOURCES

TB/HIV in-service education, skin testing training, posters, TB Directories, other educational materials and consultation are available through the Division of Tuberculosis Control (617-522-3700, x 450).

[NOTE: *Attachments are not included in this version.*CED.]

The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
Treatment Improvement Protocol (TIP) Series 18

Appendix E -- A Massachusetts Pamphlet on HIV and TB

This appendix is not available in electronic format. To obtain a hard copy of TIP 18, The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Abuse Treatment Providers, contact the National Clearinghouse for Alcohol and Drug Information (NCADI), (800) 729-6686, or access NCADI's web site at http://ncadi.samhsa.gov/. The reference number for this TIP is BKD173.

The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
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Appendix F -- A Massachusetts Pamphlet on the Connection Between Substance Abuse and Certain Communicable Diseases

This appendix is not available in electronic format. To obtain a hard copy of TIP 18, The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Abuse Treatment Providers, contact the National Clearinghouse for Alcohol and Drug Information (NCADI), (800) 729-6686, or access NCADI's web site at http://ncadi.samhsa.gov/. The reference number for this TIP is BKD173.

The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Treatment Providers
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Appendix G -- New York State OASAS Administrative Bulletin on TB Control In Drug Treatment Programs

New York State Office of Alcoholism and Substance Abuse Services ADMINISTRATIVE BULLETIN

No. 93 - 03

Date: August 7, 1992

MARGUERITE T. SAUNDERS, Commissioner

TO: All Treatment Providers, Local Government Units, Local Designated Agencies

SUBJECT: Tuberculosis Control

This Administrative Bulletin is the second transmittal on tuberculosis since February 1992. The first was sent to DSAS providers and included information and recommendations on TB control for drug treatment programs. The February Bulletin is attached for your information.

New York State has the highest incidence of tuberculosis in the nation. New York City has been particularly hard-hit, with a TB case rate (number of cases per 100,000 people) five times the national average (50 cases vs 10 cases).

The dramatic increase in tuberculosis has significantly affected drug and alcohol abusers, particularly those with HIV infection. The emergence of multiple drug resistant strains of TB (MDR-TB) has further contributed to the concerns of providers about the health and safety of their clients and staff.

This Bulletin has several purposes:

- Communicate additional information on the activities of the Office of Alcoholism and Substance Abuse Services (OASAS) in this area.
- Establish minimal requirements for all drug and alcohol treatment providers in the area of TB control and prevention.
- Transmit information on the establishment of a TB control program from the State Department of Health (DOH Memorandum 92-7) and where appropriate, encourage provider participation in DOH programs.

This Bulletin will be updated periodically as additional scientific data on the most effective methods of TB prevention and treatment are confirmed. For presentation purposes, this Bulletin will adopt the framework of the attached DOH Memorandum 92-7, "Control of Tuberculosis in Hospitals."

I. Program TB Policy Review

All programs should immediately initiate a thorough review of their existing policies and procedures on TB control and prevention. Using the attached DOH Memorandum 92-7 as a referral, all programs should:

- review existing policies and procedures concerning:
    - early identification and treatment of TB clients and staff;
    - environmental control;
    - employee screening;
    - current strategies for cooperation with Public Health Authorities;
    - current strategies on client's compliance with TB medication.
- produce and make available to employees a written copy of the policies and procedures governing TB control and prevention in the program;
- educate employees about tuberculosis and TB prevention; i.e.,
    - the cause and transmission of TB
    - definition of infectious TB and the distinction between TB disease and infection;
    - the signs and symptoms of TB;
    - the factors associated with disease development (e.g., HIV);
    - TB screening and follow-up;
    - Anergy;
    - compliance with TB medication regimen (including discussion of side effects of medications, MDR-TB and the role of DOT).

To assist programs in developing education programs, a copy of the Centers for Disease Control Core Curriculum on Tuberculosis is enclosed with this Bulletin. Further information and assistance is available through the County Health Department in your area. For additional assistance from OASAS, contact Rebecca Rosenfeld of the AIDS Resource Unit at (212) 870-8498.

II. Early Identification and Treatment of TB

The best method of TB control is early case finding and treatment. It is essential that any TB control program recognize this priority: clients with active TB must be identified and treated.

Completion of TB therapy is crucial in preventing the spread of TB including multiple drug resistant TB (MDR-TB). Noncompliance with TB treatment is common because TB disease must be treated for a long time (6-18) months) after hospital discharge and regimens for treatment of TB must contain multiple drugs to which the organisms are susceptible. Noncompliance is a major problem in TB control; when patients fail to complete their drug

therapy they not only become sick again, but they may also become infectious again thereby spreading the disease. The drug and alcohol provider community must play a primary role in ensuring that their clients complete their therapy.

The New York State Department of Health Directly Observed Therapy (DOT) Program may assist some providers with reimbursement for helping their clients take their TB medications. Currently this reimbursement program is open to Article 28 drug and alcohol treatment programs with Medicaid patients; however, it is anticipated to be expanded to Article 31 alcoholism treatment programs and other substance abuse providers. All Article 28 drug and alcoholism treatment providers in New York City may qualify as a Level I or Level II provider. Eligible programs should consider enrollment in the DOT program to offer these services to their clients with active TB. OASAS is working with the State Department of Health on the DOT model's responsiveness to the needs of our provider community and clients.

Further information on the DOT program can be obtained by contacting Susan Klein at (518) 474-2353 or Brenda Naizby at (518) 474-7000 of the State Department of Health.

In addition, the New York City Department of Health can facilitate referral of your clients with active TB to DOT providers; contact the New York City TB Hotline at (212) 788-4162 for further information.

III. Environmental Control

There is understandable concern about the adequacy of some drug and alcohol treatment settings to control the spread of TB.

The safest, most secure and cost-effective method of removing TB bacilli from the environment remains somewhat unclear and a range of options are currently being examined (i.e., improvements in ventilation; installation of ultra violet lights and/or HEPA filters; use of personal protective devices). OASAS is in the process of engaging an environmental consultant to assist us and our programs in making the best choices to limit the spread of TB infection in their environment. As soon as this consultant is available, information and perhaps site review sessions will be scheduled.

IV. Client and Employee Screening for TB

A critical element in controlling the spread of tuberculosis is the early identification and treatment of persons with infectious TB. Consequently, an ongoing program of client and employee screening is an essential first step in a TB control program.

Client Screening - Since tuberculosis places other clients and staff at risk of infection, and since TB is a particular threat to HIV-infected clients and staff, it makes good sense that **all** drug and alcohol treatment providers incorporate PPD testing into their admissions process. Therefore, all programs whose license requires a physical exam or health assessment should now include a determination of each client's PPD status upon admission, either through on-site testing or

referral. Follow-up services where indicated (i.e., chest X-ray for positive results; anergy panel for negative result in an HIV-infected client) should also be conducted.

Programs **should not condition admission** on the administration of the PPD; however, one should be completed as soon as possible after admission. If there is a question of active disease based on the client's presenting symptoms (unexplained weight loss, fever, night sweats, cough, cough tinged with blood, chest pain), the client should be evaluated immediately for active TB.

All clients who are not infected with the tuberculosis bacillus should be re-tested annually.

Employee Screening - The United States Department of Labor, Occupational Safety and Health Administration and the Centers for Disease Control, recommend an employee screening program for personnel who work with substance abusers, and have issued guidelines on employee screening for TB that include:

- pre-employment screening
- six month screening for workers at the highest risk of exposure; annual testing for all other personnel
- Positive reactors should be referred to their personal physician for additional diagnostic tests and treatment if needed.

All licensed treatment program should immediately initiate an employee screening program with staff members at highest risk re-tested every six months if negative. All other staff members should be tested yearly.

New employees should be tested upon hire unless there is a previous positive test. Programs should move aggressively to develop baseline PPDs on all staff members.

V. Cooperation with Public Health Authorities

The New York State Department of Health and the local Departments of Health have the lead responsibility for the management and control of tuberculosis.

Cooperation with public health authorities in TB control projects poses special problems to drug and alcohol providers because of Federal confidentiality restrictions. Resolution of the tension inherent in the approaches of the two systems concerning the use of patient identifying information is possible through the use of the appropriate safeguards. To facilitate this communication, programs should seek a written informed consent from clients on admission which would permit communication with the local health authority if the patient develops clinical TB.

VI. OASAS Task Force on Tuberculosis

In developing a comprehensive strategy on TB prevention and control, a coordinated response which is grounded in an ongoing dialogue with the provider community is essential to success. Consequently, an OASAS Task Force on Tuberculosis has been formed to coordinate actions to

meet the needs of clients and employees of the OASAS and local service providers. The Task Force is working with representatives from the provider communities and other State agencies to respond to the TB epidemic on behalf of our clients and workforce.

More information about the Task Force, or the contents of this Bulletin, are available from the co-chairs:

Upstate
William Barnette
(518) 474-5102
Downstate
Francis A. McCorry, Ph.D.
(212) 870-8498
attachments
[NOTE: *Attachments are not included in this version.*CED.]

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Appendix H -- New York City TB/Methadone Registry Match Procedure

THE TB/METHADONE REGISTRY MATCH PROCEDURE

1. Each participating MMTP provider will enter into a QSOA with Creative SocioMedics (CSM) to receive the TB information generated by the cross-matching of the two tapes.
2. CSM will receive a tape of clients who are on the NYC Department of Health (CDoH) TB registry (for the period 1992 to present) as: open i.e. a patient diagnosed with active TB who has not completed treatment according to CDoH's registry; lost to follow-up i.e. a patient diagnosed with active TB who has not completed treatment according to CDoH's registry and who the Bureau cannot locate to obtain follow-up information; or refused treatment i.e. a patient diagnosed with active TB who has not completed treatment, and who has refused to continue treatment according to CDoH's registry. This tape will be compared with the enrollment registry of MMTP patients. CDoH will send the TB registry tape to CSM for match and distribution by the first of each month.
3. CSM will inform each participating MMTP provider of those patients who appear on both registries (a match is defined if two of the following parameters: Name; SS; DoB are the same.)
4. Aggregate data on the total number of matches would be shared with CDoH, OASAS and COMPA by CSM.
5. The MMTP provider will ascertain the patient's medical status, and ensure that proper TB treatment is being provided either on site at the MMTP or by another medical provider.
6. If the MMTP is a TB medical care provider (Diagnosis and treatment on site):
    A. Then the MMTP would seek a signed consent form from the patient for the program to initiate contact with CDoH and share relevant medical information to ensure continuity of treatment. The MMTP will then send a letter to the Director of Surveillance at CDoH informing this staff of the names of patients who have signed a consent (see attached sample letter).
    B. The Drug Treatment Liaison at CDoH will telephone a designated MMTP representative on a monthly basis (as per NYC Health Code Section 11.47) to obtain information on patient adherence and TB drug regimen. Alternatively, the MMTP provider may submit a TB 65 monthly TB reporting form.
7. If the MMTP is a non-medical care provider:
    A. For patients identified by the match the MMTP will seek a consent form to notify CDoH of the name of the client, and the name of the client's primary medical care provider (see attached sample letter for non-medical care provider). The MMTP provider is not required to report to CDoH active cases of TB (TB cases should be reported by the diagnosing physician).

B. If the MMTP provider is satisfied that the patient is receiving proper TB treatment and is posing no health danger to him/herself or to others, and the patient does not consent to release information to CDoH, this information would be entered in the patient's medical record and no information will be shared with the TB registry or any other third party.
C. If the patient does not consent and is non-compliant with TB care, a second attempt at receiving consent would be tried. Finally, a court order to allow disclosure of the patient's treatment status and non-compliance with TB care will be sought. This court order would not compel the patient to accept treatment; it would authorize the MMTP provider to report the specific information to the CDoH, which is necessary for them to locate the patient and attempt to secure compliance with medical treatment. If the program is unsure whether a court order would be appropriate, the program or its attorney may contact OASAS Counsel's Office for assistance.

[Name of MMTP Contact person]
[MMTP Address]
[Date]
Mr. Michael Williams,
Director of Surveillance
NYC Department of Health
Bureau of TB Control
125 Worth Street, Box 74
New York, NY 10001
Re: [Name of client]
DOB:
SS#:

Dear Mr. Williams:

Please be advised that the above referenced person has been identified through the TB Cross Match and is under our care for both a substance abuse disorder and for tuberculosis.

This information has been disclosed to you with the consent of the patient from records protected by Federal confidentiality rules pertaining to the records of alcohol/drug abuse program (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patients.

I trust this information is sufficient for this purposes.

Sincerely,

[Name of MMTP Contact person]
(TO BE USED IF YOUR MMTP IS A TB MEDICAL CARE PROVIDER)

QUALIFIED SERVICE ORGANIZATION AGREEMENT

_____ (hereinafter referred to as "the Program")
(Name of Methadone Maintenance Treatment Program)
and Creative Socio-Medics (hereinafter referred to as "CSM") do hereby enter into a Qualified Service Organization Agreement, whereby CSM agrees to provide the Program with relevant information, received from the New York City Department of Health, regarding the diagnosis or treatment for tuberculosis of a patient in the Program.

Furthermore, both parties to this Agreement:
(1) acknowledge that in receiving, storing, processing or otherwise dealing with any information received, they are fully bound by the provisions of the federal regulation governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and
(2) undertake to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than is expressly provided for in the federal confidentiality regulations, 42 C.F.R. Part 2.

Executed this _____ day of _____, 199__.

_____
[Print Name of Person Signing]
[Title of Person signing]
[Name of the Program]
[Address of the Program]
[Print Name of Person Signing]
[Title of Person signing]
[Name of the Program]
[Address of the Program]

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Appendix I -- New York State Division Of Substance Abuse Services Tuberculosis Update

New York State
DIVISION OF SUBSTANCE ABUSE SERVICES
Executive Park South, Box 8200 Albany, New York 12203-8200

ADMINISTRATIVE BULLETIN

Transmittal Number:92-2
Date: February 12, 1992
To:All Treatment Providers and Local Designated Agencies
Subject:Tuberculosis Update

Since the middle of the 1980's, tuberculosis has re-emerged as a significant public health problem. After three decades of decline, the number of cases of TB increased for the first time in 1986. New York City has experienced dramatic increases in cases of tuberculosis, with a 38 percent increase in one year. Currently, New York City has a TB incidence rate of approximately 50 reported cases per 100,000 persons, approximately five times the national average.

The Division issued a Medical Alert Administrative Bulletin on tuberculosis in 1988 (see Transmittal Number 88-24). This new bulletin will update you on important developments in this epidemic since 1988 and recommend several actions.

The resurgence of tuberculosis as a major health issue has significant implications for drug treatment programs. A major factor in this resurgence is the presence of HIV infections among persons who develop clinical tuberculosis. In one study conducted at the methadone treatment program of Montefiore Medical Center, all eight MMTP patients who developed active TB were also HIV-infected. Seven of the eight cases involved the reactivation of latent tuberculous infection. The Centers For Disease Control (CDC) estimate that approximately 90 percent of the new cases of TB occur in persons with latent tuberculous infection, which is reactivated when their immune system, weakened by HIV or other causes, is no longer able to control the TB infection.

Multiple Drug Resistant TB (MDR-TB)

The development of drug resistant strains of TB that do not respond to the first line drugs currently used for treatment of tuberculosis is a matter of serious concern. A recent study of the hospitalized cases of TB in New York City revealed that 34 percent had TB strains that were resistant to one or more of these first line TB medications. Consequently, MDR-TB must be treated for longer periods of time with drugs that have significantly increased toxicity and require

careful patient monitoring. In immunocompromised patients (e.g., HIV disease), MDR-TB has often been fatal.

In March 1991 the CDC reported on the transmission of a drug resistant strain of TB (resistant to isoniazid, rifampin, and ethambutol) in a residential drug treatment program in Michigan. The program treated 140 clients in a two-story building with dormitory-style living arrangements. One client with MDR-TB is known to have infected at least 15, and possibly as many as 31 persons (one staff person).

Non-compliance with the full course of drug treatment for active TB (9-12 months) has been a major factor in the development of MDR-TB. In New York City, approximately 40 percent of all TB patients are non-compliant with treatment regimens. The non-compliance rate upstate is approximately 20 percent.

Drug treatment programs are a critical locus for the implementation of measures that can assist patients in the completion of the medication regimen; prevent the reactivation of latent tuberculous infection and reduce the transmission of the TB bacillus through patient education and monitoring. The Division views these goals as essential to the health and well-being of clients and program staff.

Anergy

Studies conducted in various settings among persons with HIV infection have noted that HIV infection can suppress tuberculin reactions (i.e., anergy) on the standard test for tuberculous infection even before signs and symptoms of HIV infection develop. Montefiore's MMTP reported an anergic response in 25 percent of its HIV-infected patients. The CDC now recommends that persons with HIV infection should be evaluated for anergy in conjunction with tuberculin skin testing.

Anergy testing should also be considered for persons from high risk groups (e.g., injecting drug users) who refuse HIV antibody testing or whose HIV status is unknown (see enclosed MMWR Guidelines for Anergy Testing and Management of Anergic Persons At Risk of TB).

Directly Observed Therapy (DOT)

Directly Observed Therapy (DOT) is a patient management tool which has been successfully employed to improve compliance rates among patients with clinical tuberculosis and to prevent the reactivation of latent infection.

Through the use of "sites of opportunity" where TB patients are seen regularly for another service (e.g., drug treatment), the completion of the long medication regimen can be accomplished. Patients who are no longer infectious at this stage of their illness are observed taking their TB medication when they receive their drug treatment services. The Division is working with the State Department of Health and Department of Social Services to develop funding streams and protocols which would allow payment to drug treatment programs for provision of directly observed services to their clients.

It is essential that patients with active TB complete their therapy to eliminate the development of MDR-TB and its potential spread to other clients and staff. To accomplish this, drug treatment programs, hospitals, and public health agencies must improve their communication, define their roles and coordinate their activities in managing the client with TB. The Division is working with the State and City agencies and the provider community (i.e., COMPA; TCA; State Association; Legal Action Center) to develop ways to improve the continuity of care while safeguarding client rights.

Occupational Exposure

The Division is concerned about the potential exposure of staff to the TB bacillus and recommends that programs perform baseline Mantoux skin tests on all staff, especially direct service staff (see CDC recommendations in "What Drug Treatment Centers Can Do To Prevent Tuberculosis"). Patient education sessions of TB transmission and prevention should also be conducted.

The Division is currently working with the City Department of Health to incorporate TB modules into introductory counseling courses funded by the Division and offered through NDRI. The Division is also meeting with DOH and DSS to determine what modifications in the physical plant can be readily adopted to minimize the transmission of TB in treatment settings.

Recommendations for TB Prevention in Drug Treatment Centers

The Division endorses the seven recommendations of the Centers For Disease Control for the prevention of TB in drug treatment programs as necessary strategies to be implemented by its programs:

- Routinely provide Mantoux tuberculin skin testing on-site for every person served at the center.
- Refer persons with skin test results of 5 millimeters or greater for TB evaluation.
- Refer persons with TB-like symptoms, regardless of the skin test results, for TB evaluation.
- Provide or refer for HIV counseling and testing: (1) persons with skin test results of 5 millimeters or greater; (2) persons with a part or present history of IV drug use; and (3) the sex partners of persons with a history of IV drug use.
- Follow up on all clients referred for TB evaluation and HIV counseling and testing to make sure they keep appointments.
- Ensure compliance with TB medication by providing on-site (at the drug treatment center) directly observed preventive therapy to persons who have tuberculous infection but no clinical evidence of disease. This therapy can be provided on a daily or twice-weekly basis and, if possible, it should be provided at the same time the person is seen for drug treatment.
- Provide an ongoing TB screening and prevention program for workers who have regular contact with persons who have or are at risk for TB or HIV infection. This includes TB skin tests for employees at least once a year.

Drug treatment centers should work closely with their local health department TB program in planning and implementing these screening and preventive therapy recommendations. Health department TB programs can assist by: (1) training DTC staff to perform tuberculin skin testing and provide TB preventive therapy; (2) assisting with referrals and contact investigation and (3) providing consultation on how to reduce TB transmission in drug treatment centers and medically manage persons with TB infection or disease.

For further information on tuberculosis, contact Rebecca Rosenfeld of the Division's AIDS Resource Unit at (212) 870-8515.

Marguerite T. Saunders
Enclosures
[NOTE: *Enclosures are not included in this version.*CED.]

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Appendix J -- CDC: Essential Components of a TB Prevention and Control Program; and Screening for TB and TB Infection in High-Risk Populations

Mordibity and Mortality Weekly Report Recommendations and Reports: September 8, 1995/Vol. 44/No. RR-11

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Appendix K -- Federal Resource Panel

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